Federal Trade Commission
Microeconomics Conference

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What is Personalized Medicine?

“Getting the right treatment, to the right patient, at the right dose, at the right time.”

– When used in the context of R&D, it primarily refers to diagnostics and targeted therapeutics

– When used in a broader context, it expands to include technologies and tools influencing decisions by both clinicians and patients
Targeted Treatments: Herceptin

• Her2/neu is over-expressed in 25-30% of breast cancer cases

• Herceptest® is an protein-based test designed to identify subsets of patients with tumors that over-express the Her2/Neu receptor

• Herceptest®/Herceptin® approaches have demonstrated a success story for target/therapy combinations

Images from Ellis et al. (2005) J Clin Path. 58. 710-4
The Overlap of Personalizing Medicine and Care

Treatment Summary

- Removal of the testicle
- Surgery involving the brain
- **One round of BEP** (Bleomycin, Etoposide and Platinol)
- Three rounds of VIP chemotherapy (Ifosfamide, Etoposide and Platinol.)

Risks Associated with Tx

- 2X Risk of a second cancer
- Bladder or urinary tract toxicities
- Risk of cardiac problems
- Fertility and sexuality concerns
- Ototoxicity (hearing loss, tinnitus)
- Peripheral neuropathy
- **Lung (pulmonary) Complications**
Personalized Medicine and Patient Decision-Making

“For Gen Y woman with cancer risk, ‘it's just a boob’ ”
(CNN.com article July 17, 2009)

BILATERAL PROPHYLACTIC MASTECTOMY

• 90% risk reduction in occurrence in high-risk women and BRCA carriers
• Pain, discomfort, and loss of sexual enjoyment commonly reported
• Feelings of regret are uncommon

Tuttle. 2010.Curr Onc Rep
Broad Market for Personalized Med.

Personalized Medicine and Regulation

Brother! You doubting Thomases get in the way of more scientific advances with your stupid ethical questions! This is a brilliant idea! Hit the button, will ya?
• Is the existing institutional/regulatory framework set up to promote the development of personalized medicine?

  – Very complex question
  • Clinical research: sub-populations, responders versus non-responders, complex analytics/statistics in clinical trial design
  • FDA: Risk/Benefit, “Safe and Effective”
  • CMS: What should be paid for?
  • Intellectual property – what data can be shared and who owns it
  • Market forces: What is the incentive to create a new drug targeted to smaller populations
CURRENT ISSUES: WHO OWNS THE GENOME?
CURRENT ISSUES: DEVELOPING RATIONALE
DRUG COMBINATIONS

Nature 455, 1061-1068 (23 October 2008)
CURRENT ISSUES: GENOMICS IS HERE...
Disruptive Innovation and Precision Medicine

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Effective Rate (%)</th>
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<tbody>
<tr>
<td>ONCOLOGY</td>
<td>25%</td>
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<tr>
<td>ALZHEIMER’S</td>
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<td>INCONTINENCE</td>
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<tr>
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