Cost Effectiveness & Pricing/Reimbursement
A Biotech Case Study

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Biotech Business Model

- High costs
- High risks
- Small target populations
• Business model dictates high prices

• Value based pricing

• Comparative, defensible, and sustainable pricing

• Next generation pricing models
• HER2 gene was first cloned in 1985
• Herceptin® (Trastuzumab) developed from 1990-1997 and launched in 1998
• In vitro, Herceptin has been shown to bind to HER2+ tumor cells, leading to tumor cell stasis and death and continuous suppression of HER2 activity
• Approved to treat HER2+ first line and second or third line metastatic breast cancer
• Now approved for the adjuvant treatment of HER2 positive, node-positive breast cancer
<table>
<thead>
<tr>
<th><strong>Patient Population</strong></th>
<th>MBC HER2+ patients receiving chemotherapy (1st line)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome</strong></td>
<td>Median overall survival time: +4.8 months</td>
</tr>
<tr>
<td><strong>Incremental cost effectiveness</strong></td>
<td>$145,000/QALY$^{1}$</td>
</tr>
</tbody>
</table>

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### Adjuvant Trials and Cost Effectiveness

<table>
<thead>
<tr>
<th>Clinical trial</th>
<th>NCCTG N9831 and NSABP B-31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient population</td>
<td>ABC HER2+ node+ patients receiving chemotherapy</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Risk of recurrence: -52%</td>
</tr>
<tr>
<td></td>
<td>Reduction in mortality: -33%*</td>
</tr>
<tr>
<td></td>
<td>Disease free survival: +3 yrs</td>
</tr>
<tr>
<td>Incremental cost effectiveness</td>
<td>$26,417/QALY&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

**NOTE:** risk of making coverage and reimbursement decisions based on snapshots of data

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* P value = NS

### A “Cost-Effective” Pricing Model

<table>
<thead>
<tr>
<th>Condition</th>
<th>Cost per month</th>
<th>Cost-Effectiveness (per QALY)</th>
<th>“Cost-Effective Price” per month (@ $75,000/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HER2+ MBC (population = 10K)</td>
<td>$3,243</td>
<td>$145,000</td>
<td>$1,677</td>
</tr>
<tr>
<td>HER2+ ABC (population = 30K)</td>
<td>$3,670</td>
<td>$26,417</td>
<td>$10,419</td>
</tr>
</tbody>
</table>

**Question:** what would be stakeholder reactions to such price increases?
Delivery System Obstacles to Implementation

• ASP based reimbursement

• J codes

• Claims processing system logic

• Drug distribution

• What of the wisdom of markets?
The Challenge of Healthcare Affordability

- Drug costs and profits are a very small portion of overall healthcare spending

- Addressing fundamental inefficiencies in administration and delivery of care is key to long term success

- Let’s not risk undermining medical innovation only to achieve a false sense of security
• Herceptin as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel, is indicated for the adjuvant treatment of patients with HER2-overexpressing, node-positive breast cancer.

• Herceptin as a single agent is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have received one or more chemotherapy regimens for their metastatic disease.

• Herceptin in combination with paclitaxel is indicated for treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have not received chemotherapy for their metastatic disease.
Herceptin administration can result in left ventricular dysfunction and congestive heart failure. Serious infusion reactions and pulmonary toxicity have occurred; rarely these have been fatal. Exacerbation of chemotherapy-induced neutropenia has also occurred. The most common adverse reactions associated with Herceptin use were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia.