Global Value Committee
Review of Zyprexa

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Wednesday, August 28, 2002
Objectives

- Provide a brief overview of
  - Brand Strategy
  - Health Outcomes Research Strategy
- Review Health Outcomes Research issues
- Identify information/data gaps
- Outline action plans and assign responsibility
Brand Strategy Overview
Strategic Intent

$6 billion by 2006.....delivering linear growth!!

Average growth per year from 1997-2001 = $589 million
Zyprexa Strategy

- **What makes Zyprexa special?**
  - ZYPREXA is the Collaborative, Dedicated Leader that offers the **Dependable Control** you need to establish a more effective **Therapeutic Alliance** so you can help your patients begin to move their lives forward and realize their potential.

- **What are the Zyprexa core message elements?**
  - Dependable control
  - Therapeutic Alliance
  - Helping to Move Lives Forward
The Choices we made!!

Rationale

- Largest $ volume segments
- Leverage current Zyprexa brand equity/volume strengths and new indications/forms
- Competitive vulnerabilities to be exploited
- Lower price sensitivity vs segments 5 and 6
- Fits with company core competence as leader in neuroscience

Zyprexa Brand Territory

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Realize the Zyprexa Brand Promise:

ZYPREXA is the Collaborative, Dedicated Leader that offers the Dependable Control you need to establish a more effective Therapeutic Alliance so you can help your patients begin to Move their lives forward and realize their potential.

**Marketing Objective #1:**
Drive Zyprexa positioning through the superior delivery of the Brand Promise elements.

**Metric:**
Brand Equity Tracking Tool (consistent improvement in targeted parameters)
Anticipate and provide timely, credible and relevant answers to effectively address marketplace issues.

Marketing Objective #2: Achieve positioning goals for targeted issues.

Metric: Improved relative marketplace perceptions as measured by the Brand Equity Tracking Tool:

Weight gain
Hyperglycemia/diabetes
DKA
Triglycerides
Other emergent issues
CSF 3: Proactively Position the Competition

Proactively influence the use of competitive products and assertively protect the position of Zyprexa as the market leader.

Marketing Objective #3: Achieve positioning goals for targeted competitors.

Metric: Improved relative marketplace perceptions as measured by the Brand Equity Tracking Tool and competitive monitoring system relative to:
- Risperidone (Depot)
- Aripiprazole
- Seroquel
- Geodon
- Depakote
- Other
CSF 4: Pursue Unrestricted Access

Pursue / maintain equal and unrestricted access in Top Nine markets by demonstrating the superior value of Zyprexa in target segments

Marketing Objective #4: In partnership with BC affiliates, establish/maintain the superior Value of Zyprexa with target customers

Metric: Performance on Pricing Architecture Tool: Zyprexa within target price/value quadrant
CSF 5: Fuel the Future/Build the Business

Grow the Zyprexa franchise in schizophrenia and bipolar and realize two significant new opportunities for brand expansion.

Marketing Objective #5: Develop the brand map for new opportunities (Q3 2002) and commercialize two opportunities by 2004.

Metric: Evolve and implement the product life cycle plan to achieve linear growth through ‘06.

Areas of Focus
• High Dose
• Borderline
• Bipolar Depression
• Child and adolescent
Core Message Elements & Core Value Message Element Integration
Core Message Elements

The SDDS/NRT process will deliver data dissemination events to the 9 message categories detailed here:

1. Wide range effectiveness
2. Dependability in multiple formulations
3. Count on it to control
4. Known and manageable side effects
5. Thinks more clearly
6. Bond emotionally
7. Enduring efficacy and relapse less
8. Realize an individual’s potential
9. Better patient outcomes at equal total cost

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Core Message Elements with Core Value

Message Elements

1. Wide range effectiveness
   - Schizophrenia is a significant burden on families and national economies
   - Bipolar disorder is a significant burden on families and national economies

2. Dependability in multiple formulations

3. Count on it to control
   - For symptom control patients prefer Zyprexa

4. Known and manageable side effects
   - Patients on Zyprexa use equal or fewer side effect medications

5. Thinks more clearly
   - Patients using Zyprexa demonstrate better social functioning because of their ability to think more clearly

6. Bond emotionally
   - Patients using Zyprexa are better able to bond emotionally both with physicians, other caregivers and family members

7. Enduring efficacy and relapse less
   - The symptoms of patients using Zyprexa improve over time resulting in less relapse, rehospitalization, suicide and caregiver burden

8. Realize an individual’s potential
   - Zyprexa is better able to return patients to meaningful, fulfilling and productive lives (QOL)

9. Better patient outcomes at equal total cost
   - Zyprexa produces better patient outcomes in schizophrenia and bipolar disease with no incremental cost
Prioritized Core Value Message Elements

Demonstrate superiority to Atypicals (Risperdal: oral/depot, Seroquel, Geodon, Abilify), typicals & mood stabilizers (Depakote & Lithium)

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<th>Priority</th>
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Health Outcomes Research

Strategy and Plans
Health Outcomes Research Strategy

- Align with Brand Strategy
- Provide data to support the Brand Promise & Core Value Message Elements
- Generate data from pivotal studies to support affiliate reimbursement/access discussions
- Focus on Brand Council affiliates (US, UK, Canada, Australia, France, Spain, Germany, Italy, and Japan)
- Facilitate shared learning between Brand Council affiliates
Health Outcomes Research Action Plan

- **Outline:**
  - review existing health outcomes body-of-evidence
  - review on-going studies with health outcomes endpoints
  - review timelines for analyses and presentation of data from on-going studies
  - review data mining opportunities
Priority ‘A’ Value Message Elements

• Zyprexa is better able to return patients to meaningful, fulfilling, and productive lives (QOL)

• The symptoms of patients using Zyprexa improve over time resulting in less relapse, rehospitalization, suicide, and caregiver burden

• Zyprexa produces better patient outcomes in schizophrenia and bipolar disease with no incremental cost (Total Costs)
Existing evidence for “Zyprexa is better able to return patients to meaningful, fulfilling, and productive lives”

- **Published Papers:**
  - Revicki, *Quality of Life Research*, 1999
  - Namjoshi, *J. Affective Disorders*, 2002

- **Published Abstracts:**
  - Badia, *Value in Health*, 1999
On-going studies to support “Zyprexa is better able to return patients to meaningful, fulfilling, and productive lives”

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- Published Papers:
  - Namjoshi, *J. Affective Disorders*, 2002
  - Edgell, *Pharmacoeconomics*, 2000

- Published Abstracts:
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  - Namjoshi, *J. Affective Disorders*, 2002
  - Obenchain, *Drug Information Journal*, 1999
  - Zhao, *Managed Care Interface*, 2002
  - Rascati, *Pharmacoeconomics*, 2002

- **Published abstracts:**
  - Rascati, *Value in Health*, 2001
  - Zhao, *Value in Health*, 2001
  - Zhu, *Value in Health*, 2002
  - Zhao, *Schizophrenia Research*, 2002
  - Spannheimer, *Value in Health*, 1999
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Priority ‘B’ Value Message Elements

- Patients using Zyprexa demonstrate better social functioning because of their ability to think more clearly.
- Patients using Zyprexa are better able to bond emotionally with physicians, caregivers, and family members.
Existing evidence for “Patients using Zyprexa demonstrate better social functioning because of their ability to think more clearly”

- Papers/Reports:
  - Jerrell, *study report*, 1999

- Published abstracts:
  - Gregor, *European Neuropsychopharmacology*, 1999
  - Badia, *Value in Health*, 1999
  - Edgell, *J. Psychopharm.*, 2002
On-going studies to support “Patients using Zyprexa demonstrate better social functioning because of their ability to think more clearly”

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Existing evidence for “Patients using Zyprexa are better able to bond emotionally with physicians, caregivers, and family members”

- Not aware of any data that directly supports “Patients using Zyprexa are better able to bond emotionally with physicians, caregivers, and family members”

- However, all the data on social functioning and social well-being discussed earlier indirectly supports “bonding emotionally with caregivers and family members”

- There however currently is no data to support “bonding emotionally with the physician”

- An on-going randomized patient study at UCLA comparing olanzapine and risperidone includes a “Therapeutic Alliance Scale”. Data from this study will be analyzed in 2004
Priority ‘C’ Value Message Elements

- Schizophrenia and Bipolar Disorder are a significant burden on families and national economies
- For symptom control patients prefer Zyprexa
- Patients on Zyprexa use equal or fewer side-effect medications
Existing evidence for “Schizophrenia and Bipolar Disorder are a significant burden on families and national economies”

- **Published Papers:**
  - Begley, *Pharmacoeconomics*, 2001
  - Rouillon, *Pharmacoeconomics*, 1997

- **NO ADDITIONAL STUDIES PLANNED**
Existing evidence for “For symptom control patients prefer Zyprexa”

- Not aware of any available data that directly supports “For symptom control patients prefer Zyprexa”

- However, an on-going initiative in Australia assesses patients’ preferences for Zyprexa using the Time Trade-Off technique

- In addition, data on “length of therapy for Zyprexa versus competitors” from the following studies serve as an excellent proxy for “preference”
  - US SCAP
  - Pan-EU SOHO
  - The National VA Study
  - Texas Medicaid
  - MEDSTAT MarketScan Study
  - IMS initiatives

- Do we need a “preference” study that directly addresses this value message element?
Existing evidence for “Patients on Zyprexa use equal or fewer side-effect medications”

- Published Abstracts:
  - Edgell, *J. Psychopharm.*, 2002
On-going studies to support “Patients on Zyprexa use equal or fewer side-effect medications”

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Summary and Gaps

- **For Priority ‘A’ Value Message Elements (quality-of-life, hospitalizations, total costs)** – there is a significant amount of published evidence for Zyprexa, and a number of on-going initiatives to build on this body-of-evidence
- Gap in our data for Priority ‘A’ Value Message Elements include data on caregiver burden

- **For Priority ‘B’ Value Message Elements (social functioning, bonding emotionally)** – there is a lesser amount of published evidence for Zyprexa, but there are on-going initiatives to get data on social functioning/well-being
- Gap in our data for Priority ‘B’ Value Message Elements include data to support “bonding emotionally with the physician”

- **For Priority ‘C’ Value Message Elements (burden-of-illness, patient preference, side-effects)** – there is a significant amount of published evidence on burden-of-illness, and a large number of on-going initiatives to address the issues related to side-effect medication use
- Gap in our data for Priority ‘C’ Value Message Elements include data to directly support patient preference, but proxy data is available
New studies planned for a 2002/2003 start

- EMBLEM (European Mania in Bipolar Disorder Evaluation of Medicines) Study
- HGHZ (US registration study for depot formulation)
- HGKA (EU registration study for depot formulation)
- National VA Diabetic Ketoacidosis Study
- Australian Bipolar Mania Prospective Observational Study
### Data Mining Recommendations...
Helping to move lives forward

<table>
<thead>
<tr>
<th>Priority</th>
<th>Message Category</th>
<th>Overview</th>
<th>Sources</th>
<th>Comparators</th>
<th>Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Realize an individual’s potential</td>
<td>Olz vs Ris QoL improvements using multiple scales</td>
<td>HGBG, HGGN, EFESO</td>
<td>Risperidone</td>
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<tr>
<td>A</td>
<td>Realize an individual’s potential</td>
<td>Olz treated pts able to pursue meaningful productive activity</td>
<td>Comparator studies 6 mos or longer with HO scales</td>
<td>Haldol, Risperidone</td>
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<tr>
<td>A</td>
<td>Realize an individual’s potential</td>
<td>Olz improves QoL in bipolar disorder</td>
<td>HGHQ, HGD, HGEH</td>
<td>Depakote, Haldol</td>
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<tr>
<td>A</td>
<td>Realize an individual’s potential</td>
<td>Pts treated with Olz have superior work status</td>
<td>Work status captured in trials HGAJ, HGBG, HGGN</td>
<td>Haldol, Risperidone</td>
<td></td>
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<tr>
<td>A</td>
<td>Realize an individual’s potential</td>
<td>Stabilized pts continue to improve their QoL with long term use of Olz</td>
<td>HGGI</td>
<td>Placebo</td>
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</table>
## Data Mining Recommendations...
Therapeutic Alliance

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</thead>
<tbody>
<tr>
<td>B</td>
<td>Bonds emotionally</td>
<td>Olz helps patients bond with family/caregivers</td>
<td>HGH, HGEH, HGAJ, HGBG</td>
<td>Haldol, Risperidone</td>
<td></td>
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<tr>
<td>B</td>
<td>Bonds emotionally</td>
<td>Olz improves social functioning</td>
<td>Longer term studies with social function scales</td>
<td>Haldol, Depakote, Ris.</td>
<td></td>
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<tr>
<td>B</td>
<td>Bond emotionally</td>
<td>Superior compliance enables a more productive therapeutic alliance</td>
<td>Comparator studies with compliance measurement scales</td>
<td>Depakote</td>
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<tr>
<td>B</td>
<td>Bonds emotionally</td>
<td>Improvement of social well being with olz treatment in bipolar pts</td>
<td>HGH, HGHQ</td>
<td>Depakote, Haldol</td>
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</tbody>
</table>
## Data Mining Recommendations… Dependable Control

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>C</td>
<td>Known and manageable side effects</td>
<td>What drives weight gain?</td>
<td>SOHO longitudinal look at wt gain</td>
<td>Risperidone, Quetiapine</td>
<td></td>
</tr>
</tbody>
</table>