

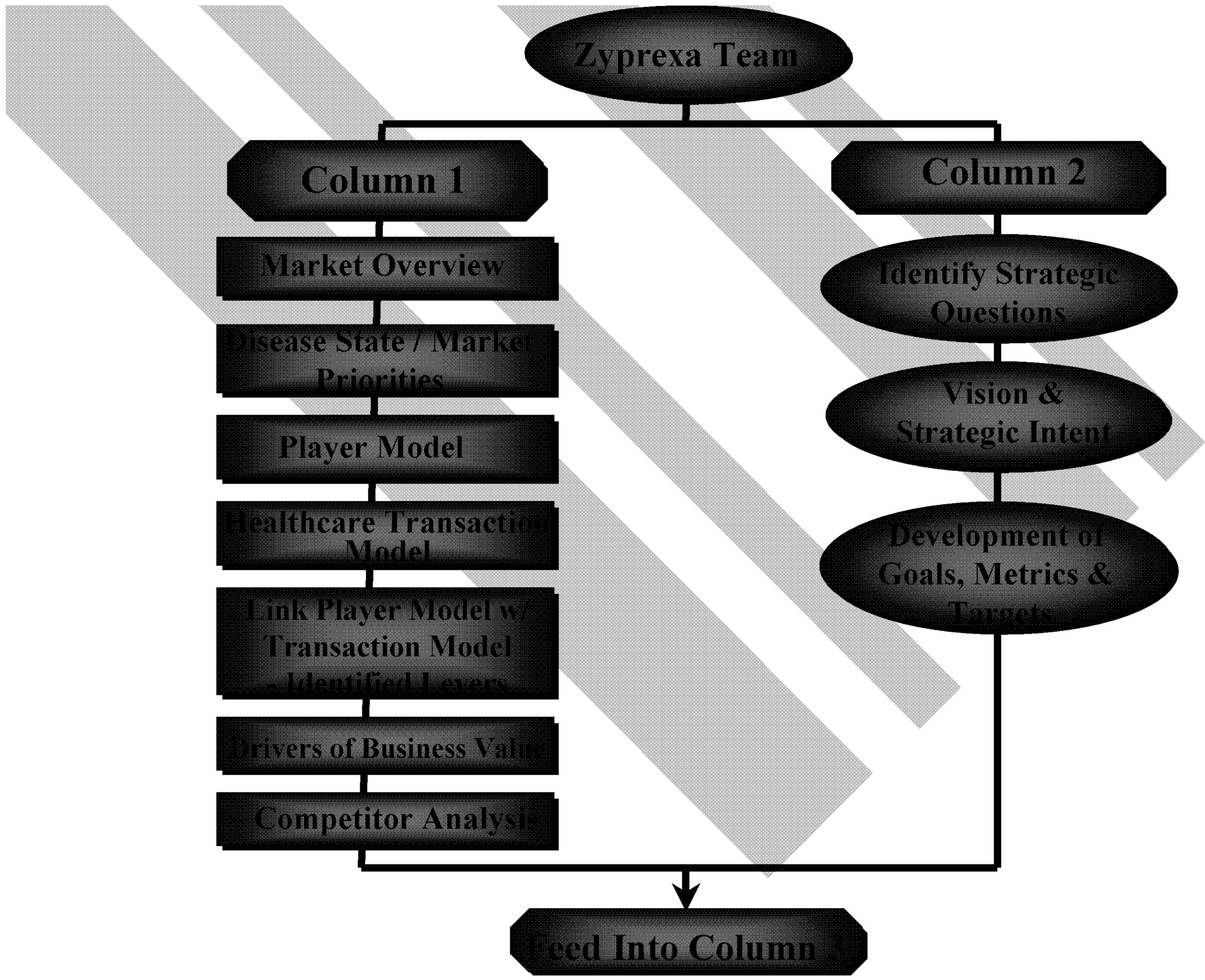
# **Zyprexa Product Team 4 Column Summary**

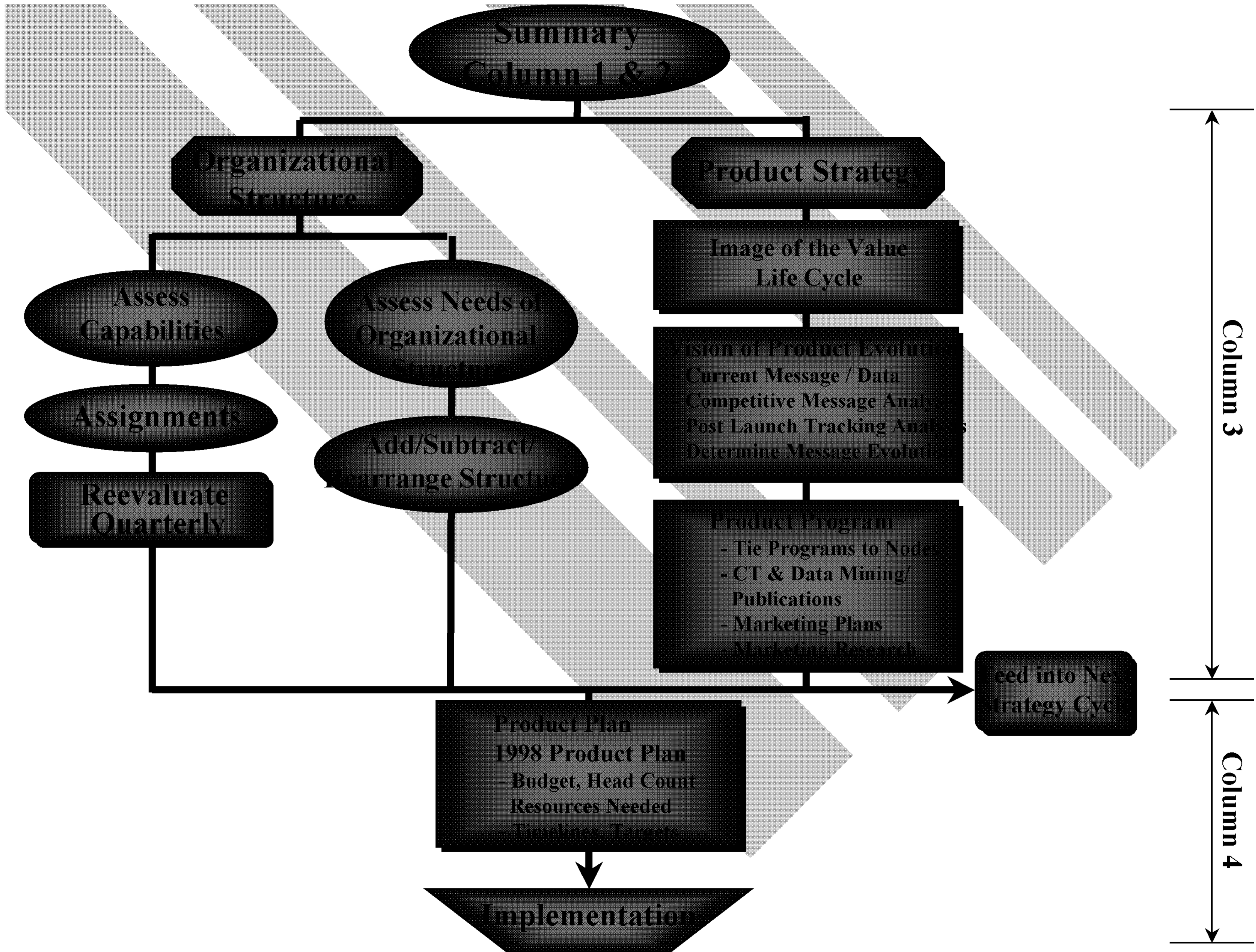
---

**Gary D. Tollefson, M.D., Ph.D.**  
**Vice President,**  
**Lilly Research Laboratories**  
**Eli Lilly and Company**  
**Indianapolis, Indiana**

# Objective/Expectations:

- Gain alignment on the magnitude of key opportunities for Zyprexa, redacted and depression including strategic intent
- Gain alignment on the core programs
- Tee - up critical issues for the next 3-year planning cycle
- Agree on the deliverables for the February Policy Committee Meeting





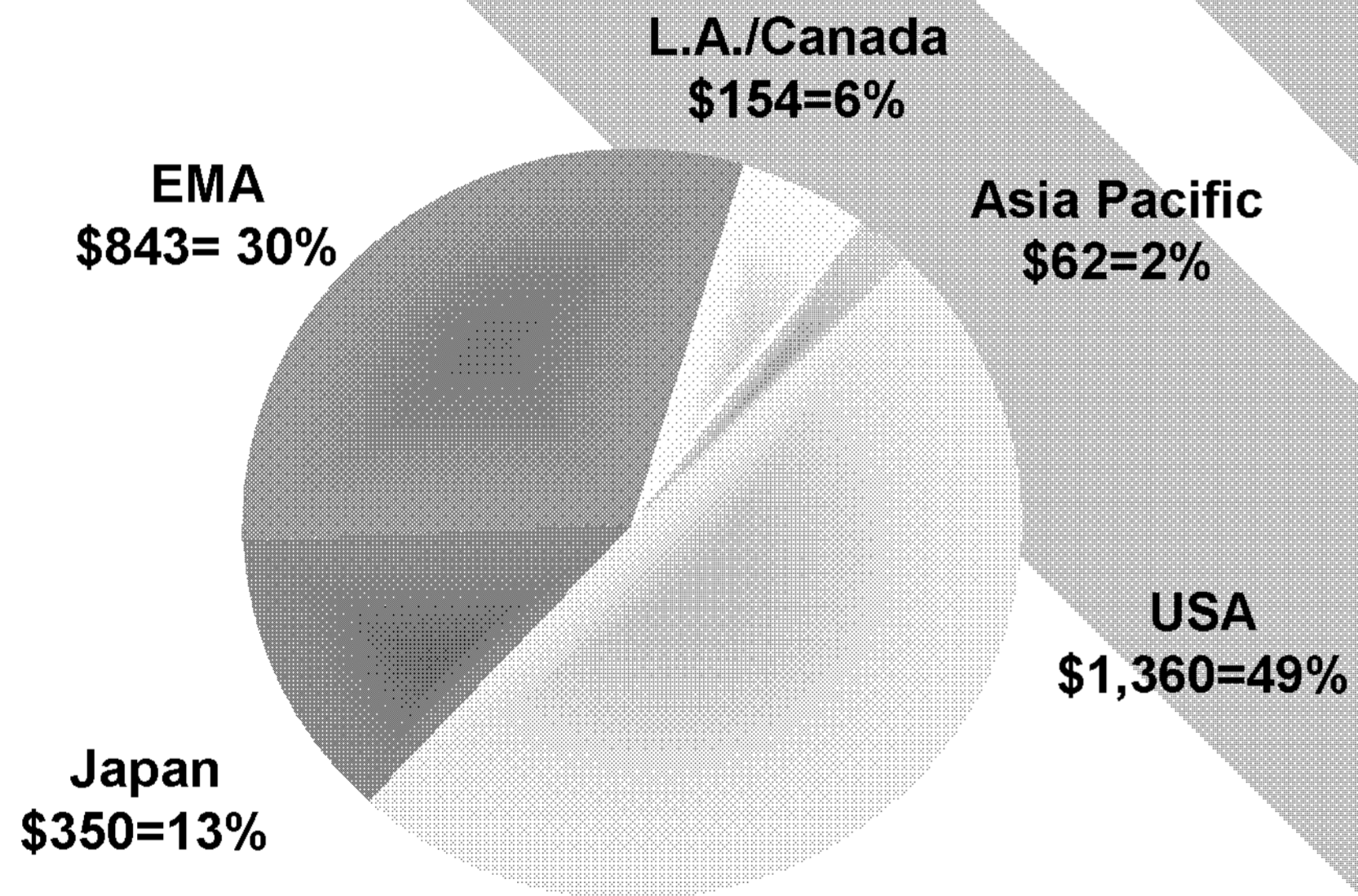
# **Zyprexa Product Team Strategy Document**

## **COLUMN I: Analyses and Givens**

- Market Overview
- Disease State Priorities
- Key Players
- Health Care Transaction
- Business Fundamentals
- Competitor Analyses

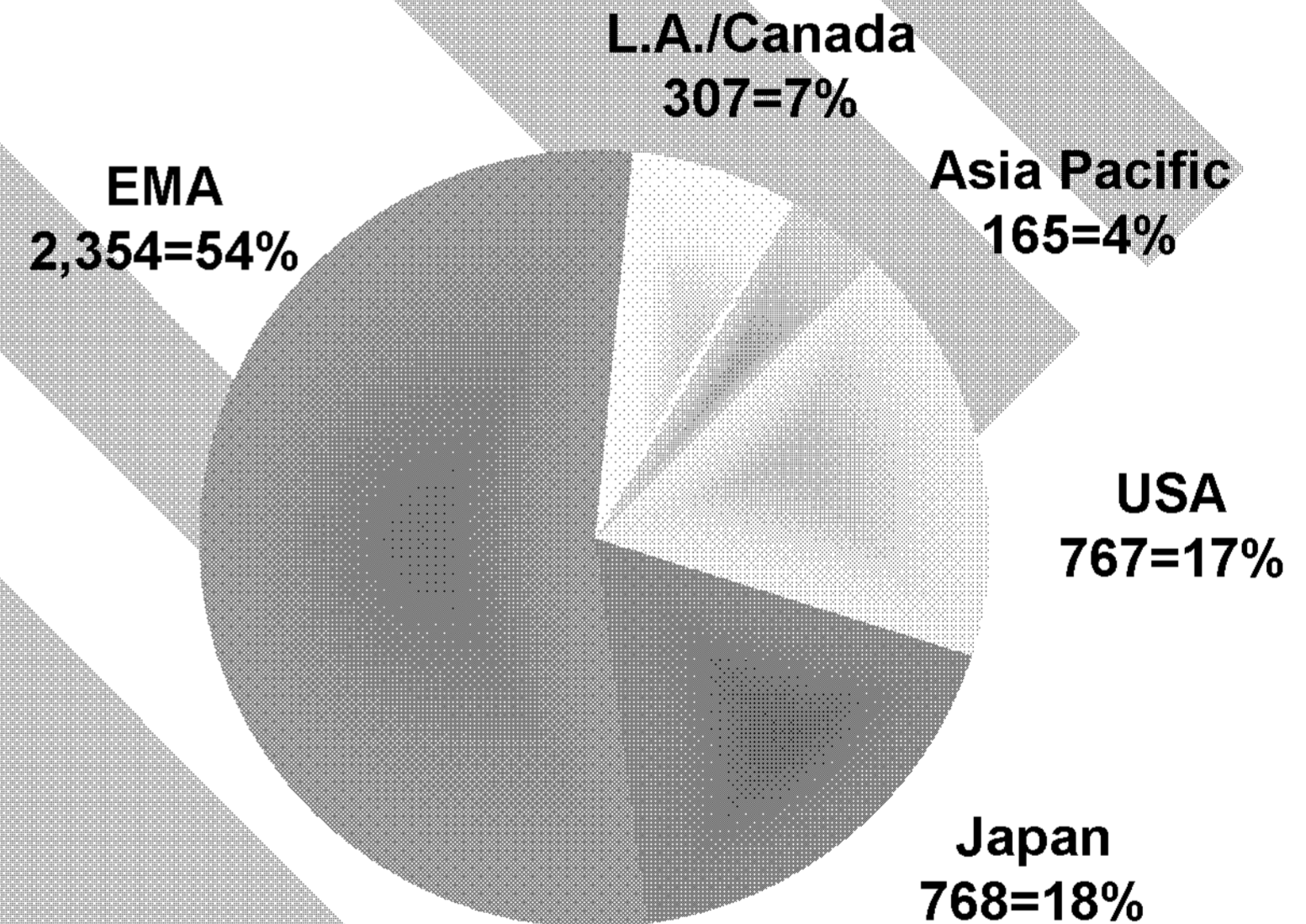
# MAT Q2/97 Worldwide Neuroleptic Market

## \$ Split



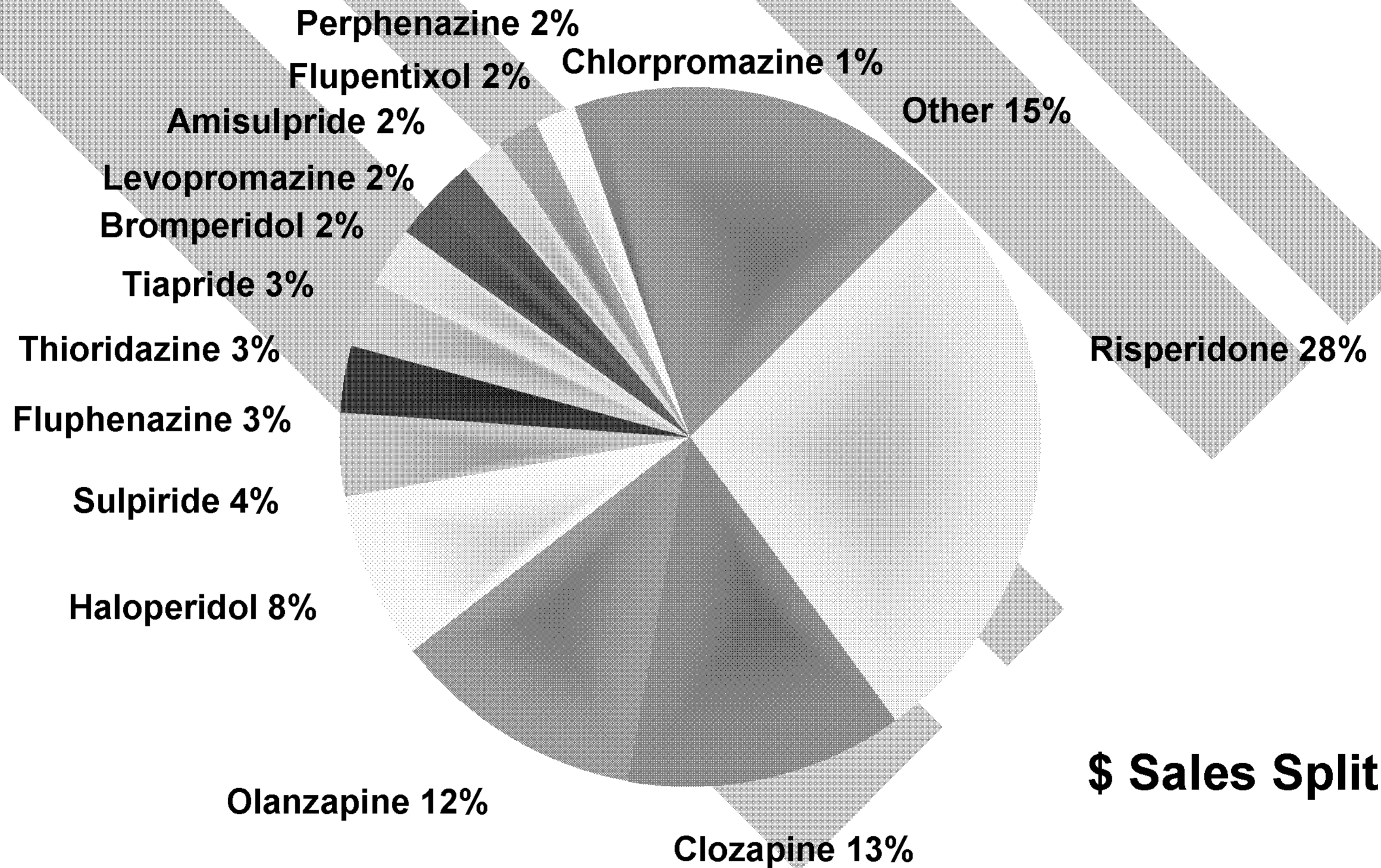
**Total World US\$ = \$2.8 billion**

## DOT Split



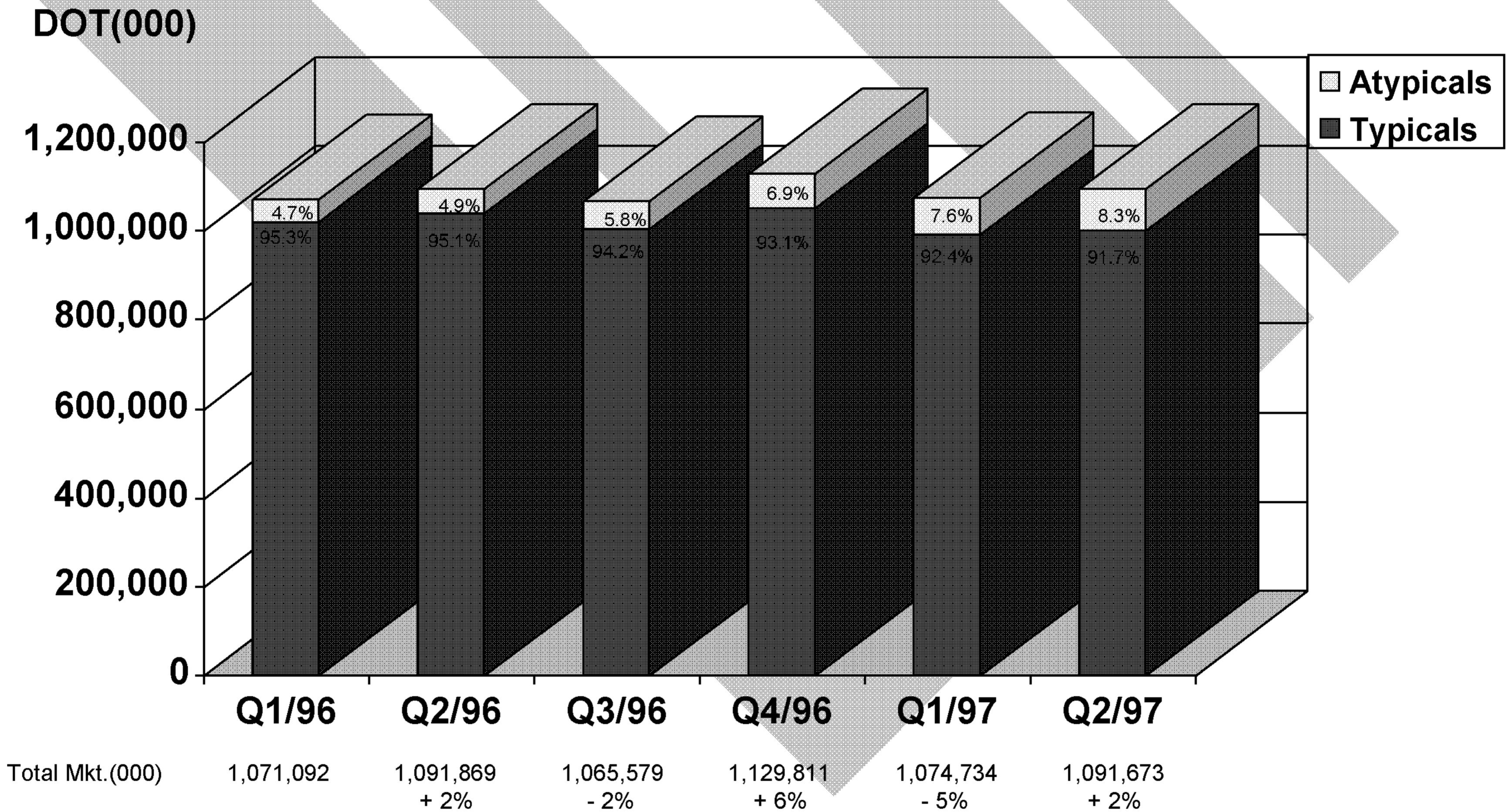
**Total World DOTs = 4.4 billion**

# Top 15 Neuroleptice Products Worldwide MAT Q2/97



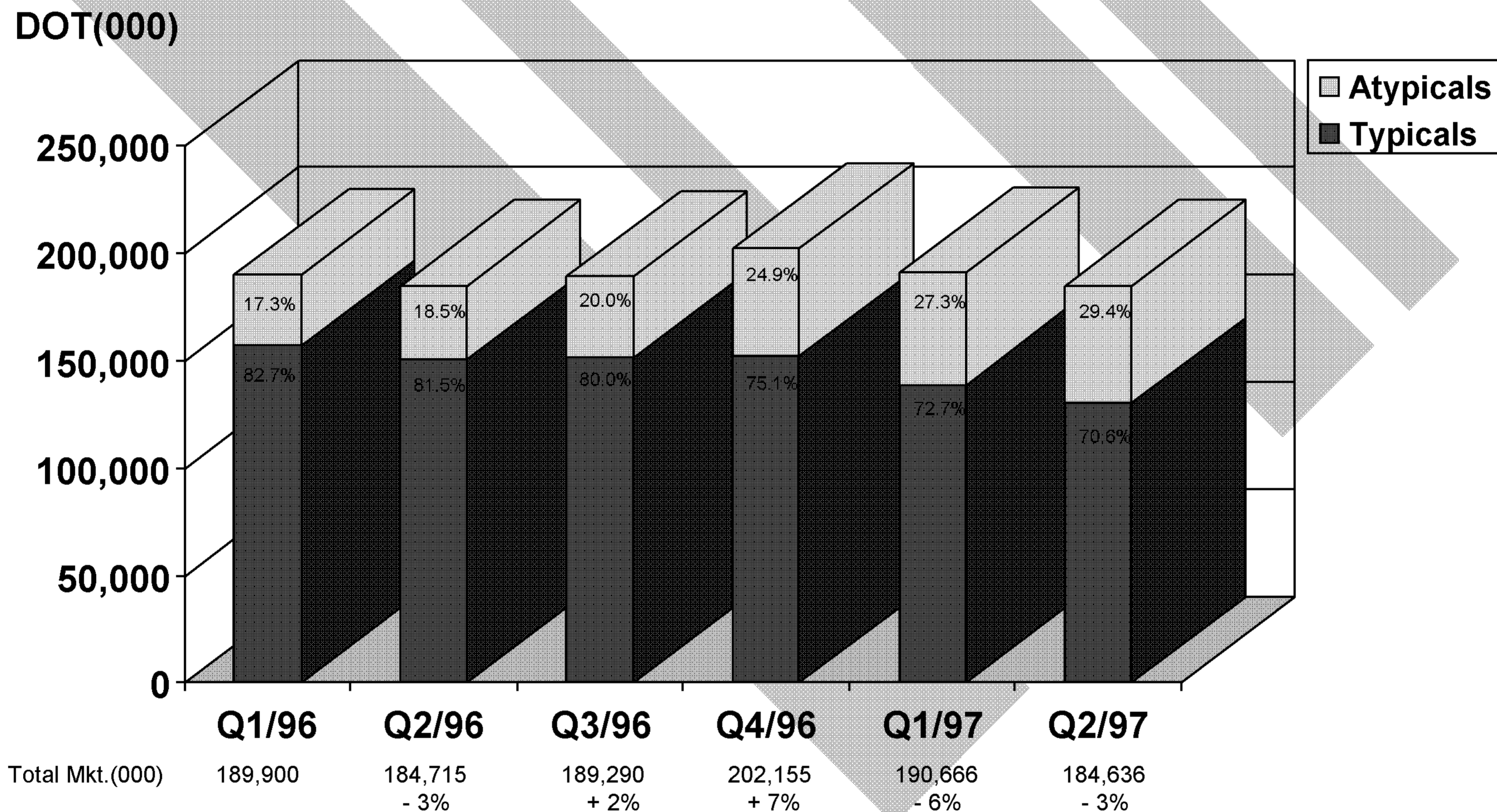
**\$ Sales Split**

# Worldwide Antipsychotic Market Days of Therapy



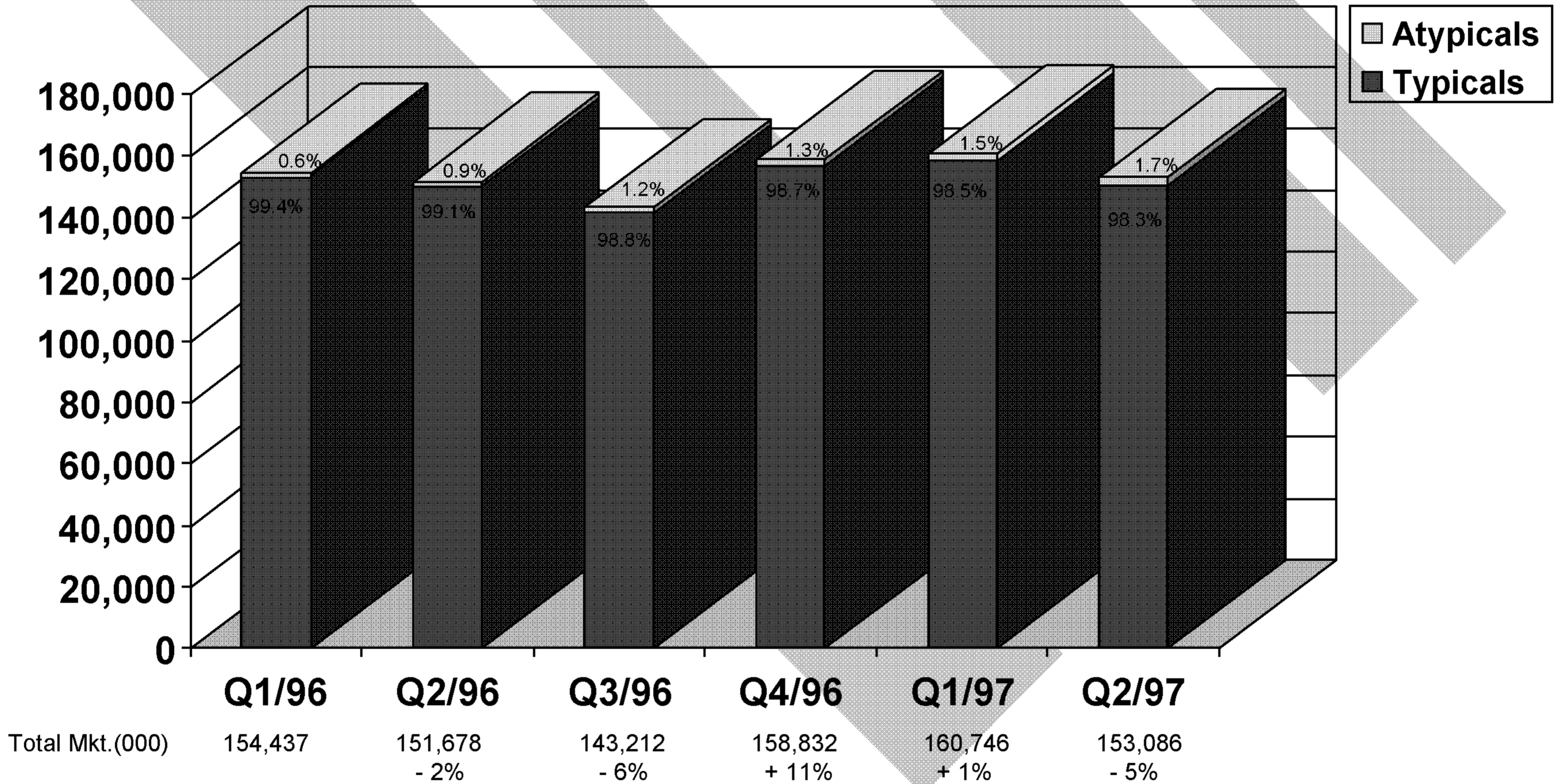


# USA Antipsychotic Market Days of Therapy



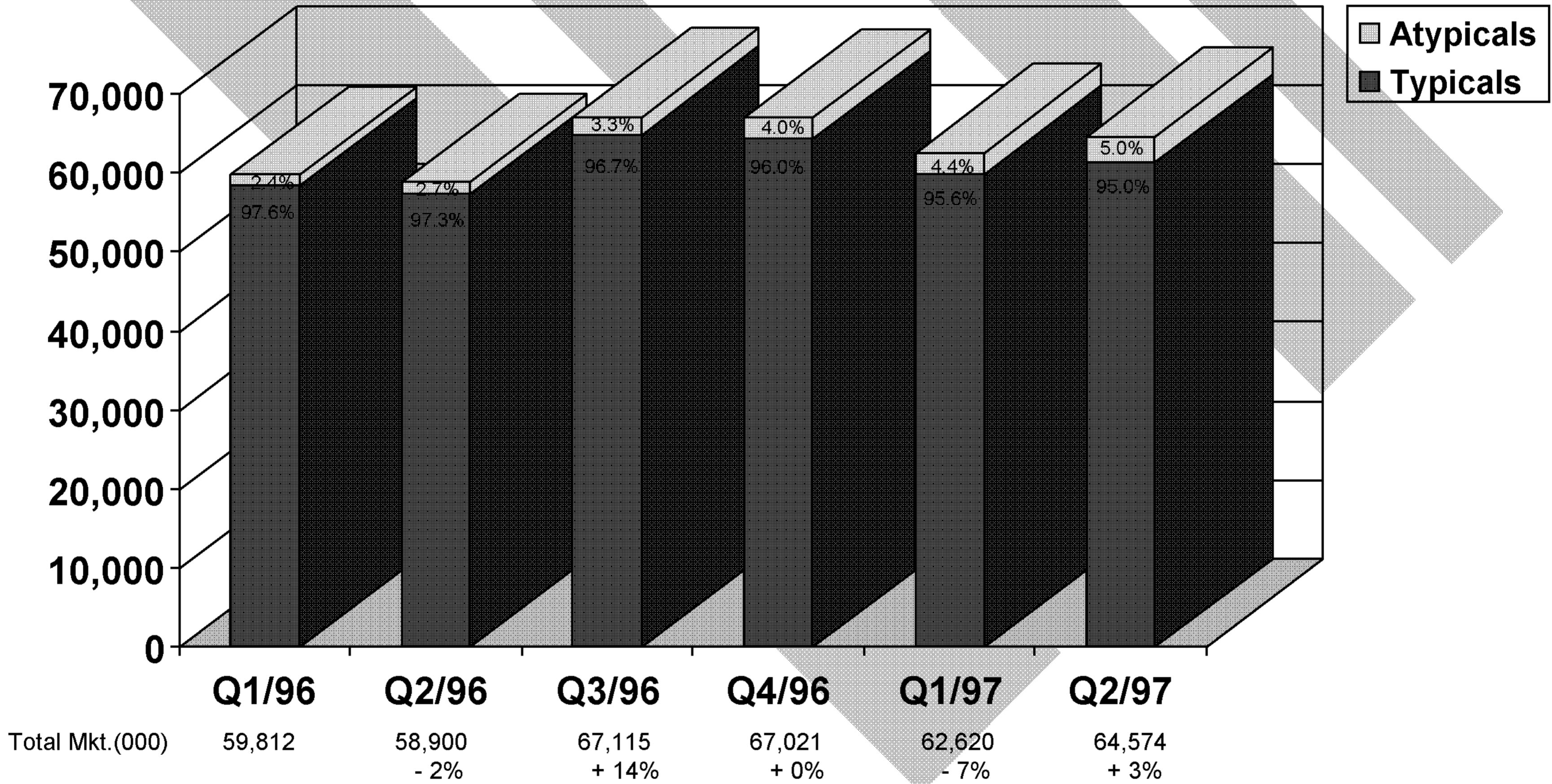
# France Antipsychotic Market Days of Therapy

DOT(000)

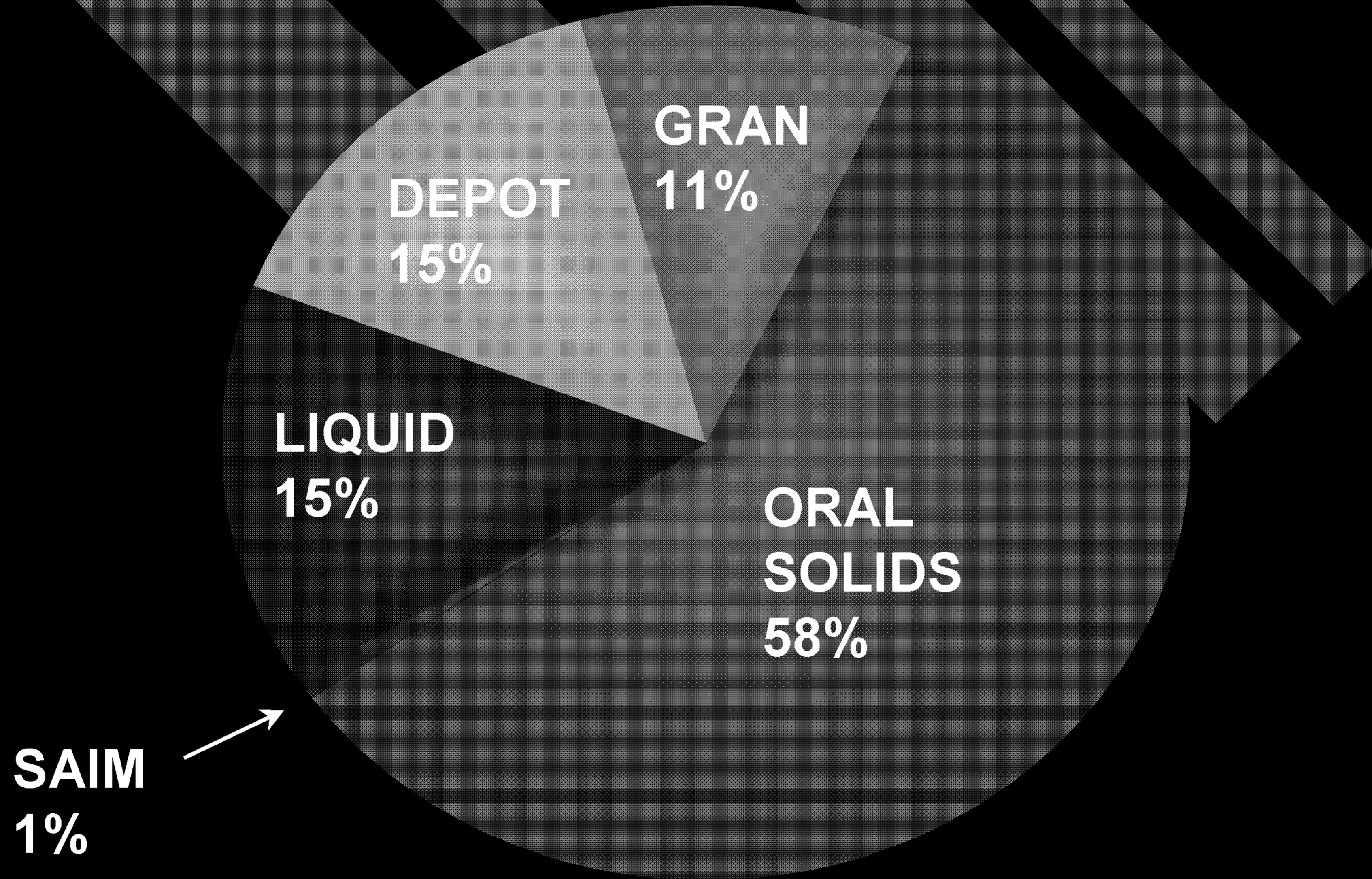


# U.K. Antipsychotic Market Days of Therapy

DOT(000)



# Neuroleptic (N5A) Market Breakout by Form



# Market Research: Drivers of Drug Choice

## Top 10

## Product Profile

## Publication

Effect on positive symptoms

▶ ▶ ▶

**Yes**

Risk of causing tardive dyskinesia

▶ ▶ ▶

**Yes**

Efficacy in refractory patients

▶

**In Press**

Patient acceptability

▶ ▶

**In Press**

Reduction of aggression/irritability

▶ ▶

**In Press**

Effect on negative symptoms

▶ ▶ ▶

**Yes**

No blood monitoring required

▶ ▶ ▶

**Label**

Reduction of anxiety/agitation

▶ ▶

**Yes**

Patient history

**“routine use”**

**1st to multi-episode**

Improvement in cognitive function

▶ ▶

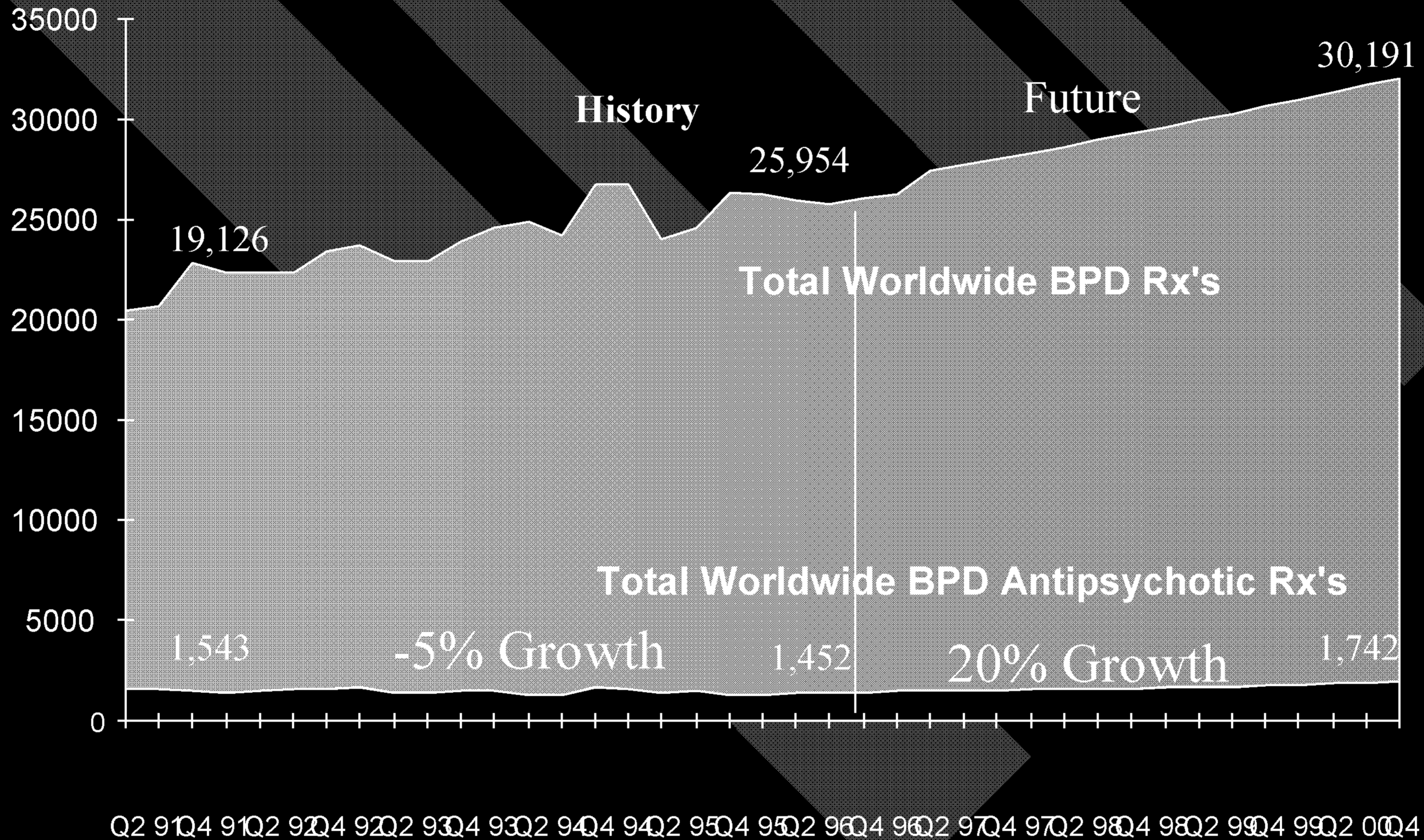
**In Press**

Risk of causing akathisia

▶ ▶ ▶

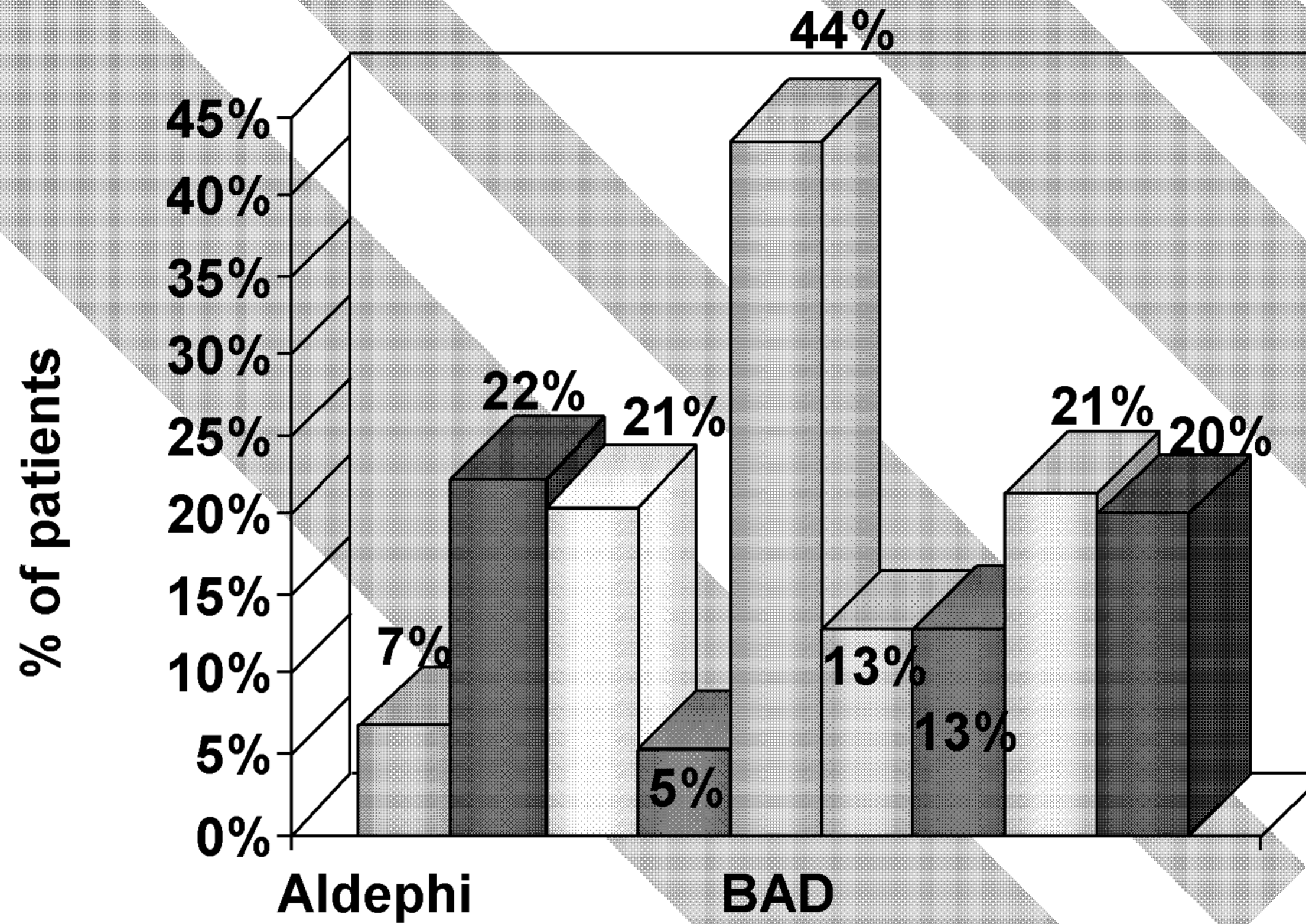
**Yes**

# Global Market Trends in Bipolar Disorder



- **36% growth in the past 6 years**
- **project  $\geq$  16% by the new millennium (7% ROW)**

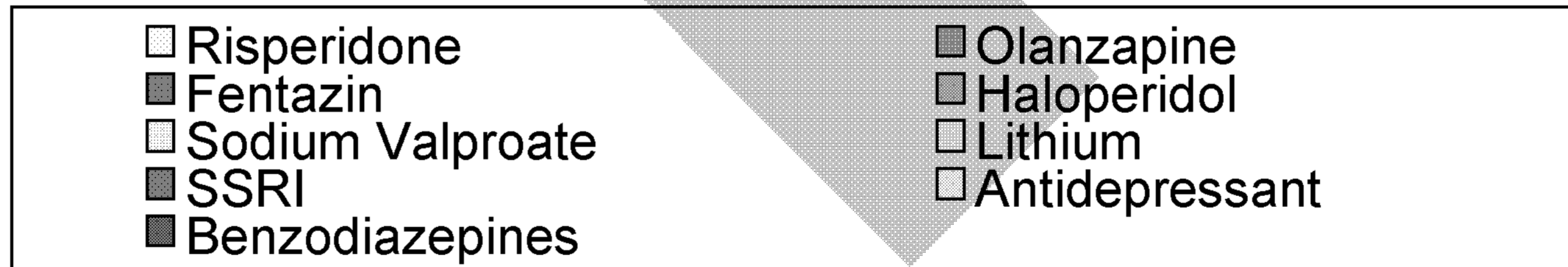
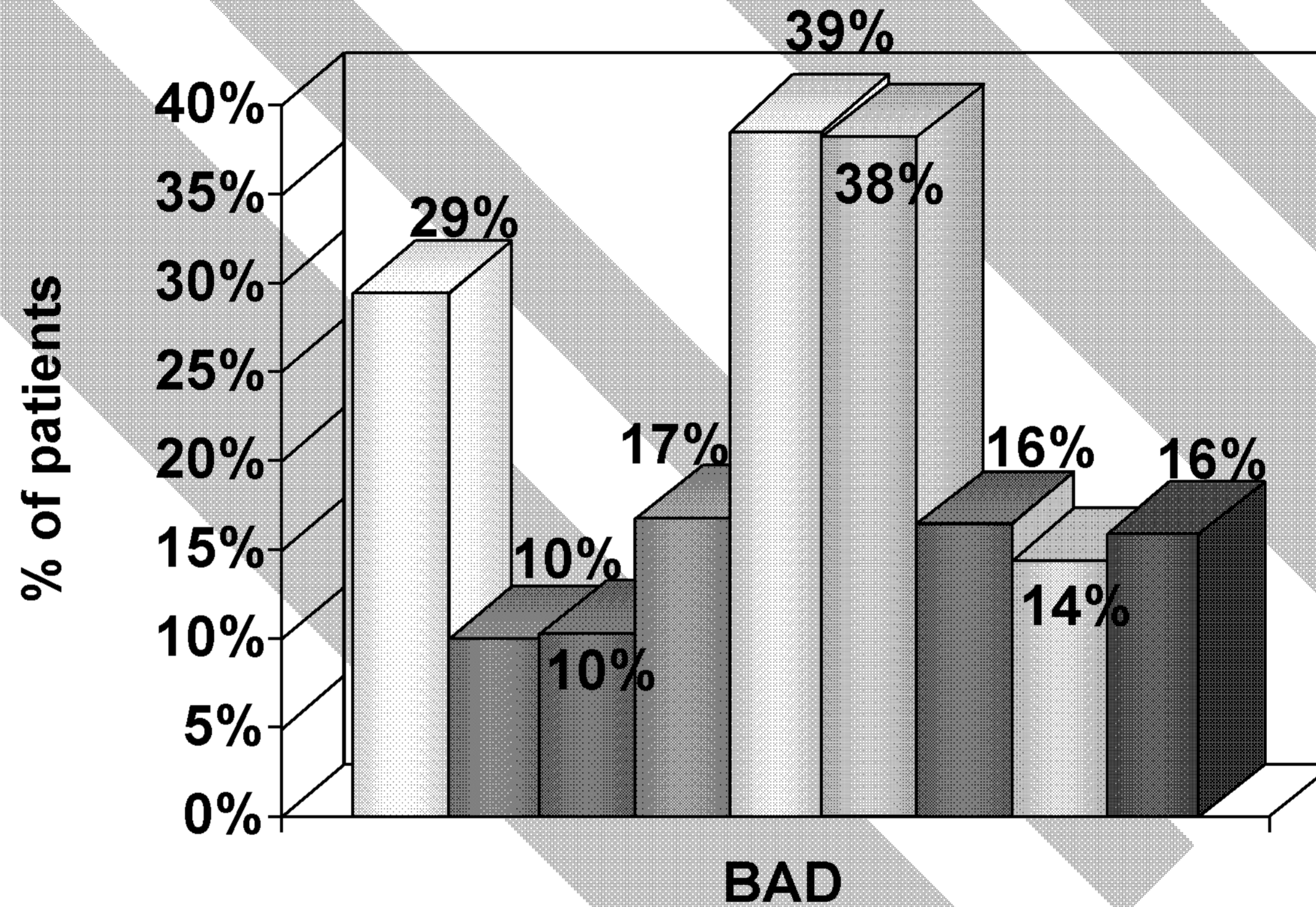
# Drugs prescribed for BPD in the Major Markets



THIORIDAZINE	HALOPERIDOL	RISPERIDONE
OLANZAPINE	LITHIUM	Antidepressants
SSRI	SODIUM VALPROATE	Benzodiazepines

- Lithium, a 28 year old product remains the leader

# Drugs Prescribed in the U.S. for Bipolar



- In the U.S., the introduction of valproate (Depakote) has been well received



# Disease State Prioritization Criteria

1. Market opportunity (1 year prevalence)
2. Unmet Medical Need
3. Probability of Technical Success
4. Halo Effect
5. Likelihood of Prescribing
6. Neuroscience Strategy
7. Promotion Potential

# Disease State Prioritization

## HIGHEST PRIORITY

### A

A significant market opportunity exists for Zyprexa and we will invest/act to take a leadership position.

- Bipolar Disorder
- Dementia with Psychosis
- Depression w/ Psychotic Features
- Dysthymia
- PD with Treatment Associated Psychosis
- Schizoaffective
- Schizophrenia
- Unipolar Depression

## SECOND PRIORITY

### B

Need to move accurately to determine the market opportunity for Zyprexa.

We will aggressively invest to gain a competitive advantage and/or blunt competitors.

- Substance Related Disorders
- Anxiety Disorders
- Borderline / Schizotypal Personality Disorders
- Aggression
- Anorexia
- *Delirium with Psychotic Features*
- Psychotic Disorders of Low Prevalence
- Schizophreniform

## THIRD PRIORITY

### C

No investment of Lilly human resources.

We will accept/find investigator initiated proposals.

- Involuntary Movement Disorders?
- Autistic Disorder
- Attention Deficit Disorder
- Bulimia / Binge Eating Disorder
- Dementia Without Psychosis
- Pain Disorder
- PMS
- Sexual Dysfunction
- Somatoform Disorder
- Vestibular Disorders
- Nausea and Vomiting
- Other Personality Disorders

## FOURTH PRIORITY

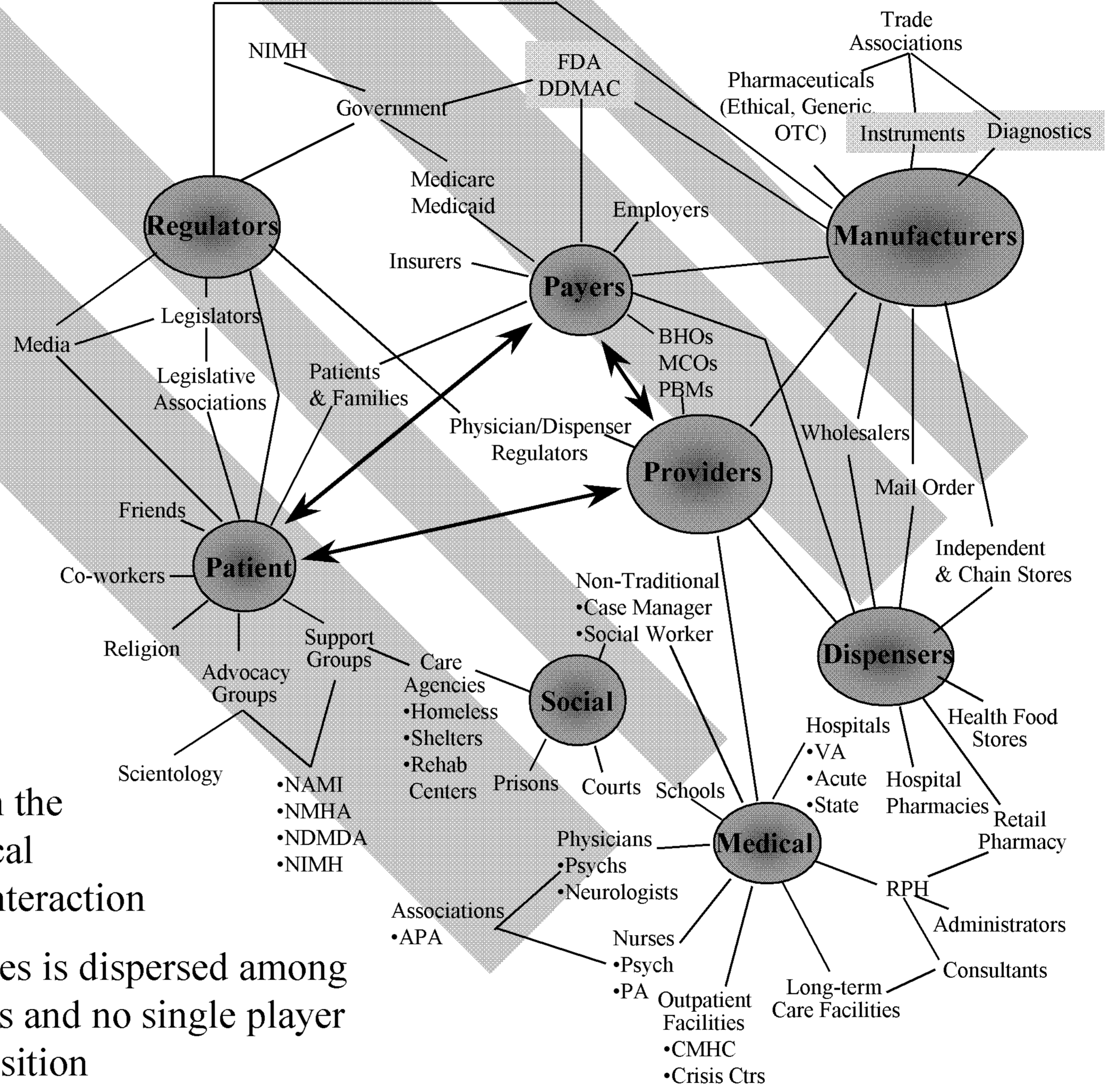
### D

No investment of Lilly Human or Financial Resources.

- Hypertension
- Epilepsy
- Trauma/Ischemia
- Incontinence
- Sleep Disorders
- ALS/MS
- Irritable Bowel Syndrome
- Asthma
- BPH
- Dissociative Disorders
- Cessation & Withdrawal from Nicotine
- Tic Disorders
- Dermatitis
- Postpartum Psychosis
- Function Bowel Disease

**Prioritize disease states opportunities to pursue new indications based on prevalence of the disorder, unmet medical need, and probability of technical success (market opportunity).**

# Key Players in the US Antipsychotic Marketplace



- The “core interaction” in the United States is the typical patient-provider-payer interaction
- Power in the United States is dispersed among a large number of players and no single player enjoys a predominant position

# *The European Antipsychotic Market*

- The role of the government is dramatically different.
- The role of the treatment team (nurses, etc.) is in most cases different.
- The role of third party payers (private insurers, employers, etc.) is substantially different.
- The number of secondary and tertiary players—and thus the number of indirect channels of influence available to a pharmaceutical company—are different.

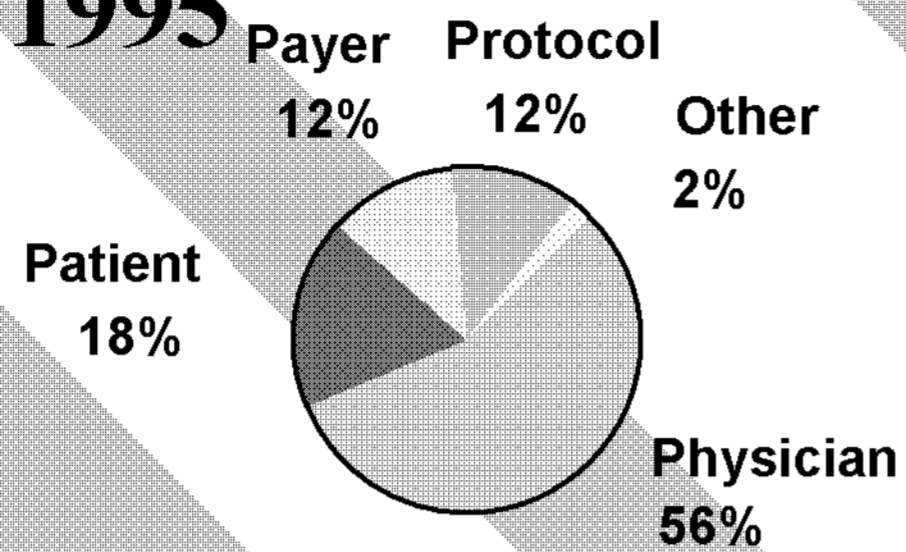
Summary: These four points would suggest that leverage points available to a pharmaceutical company are different, and thus Demand Creation programs must also be somewhat different.

# *Key Players in the Latin American Antipsychotic Market*

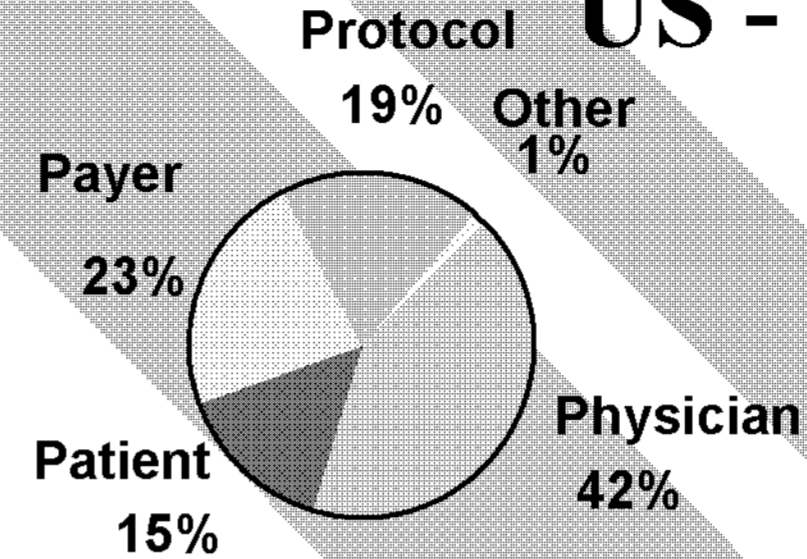
- In stark contrast to the US and European models, the core players in the treatment transaction are principally the patient and provider, as the patient is in most cases both the user and the payer.
- Also notable is the fact that power in this model is very substantially concentrated in the providers.
- The government plays a diminished role.
- As with Europe, the Latin American model is also substantially less complex than the US model.

# Key Players: Present & Future

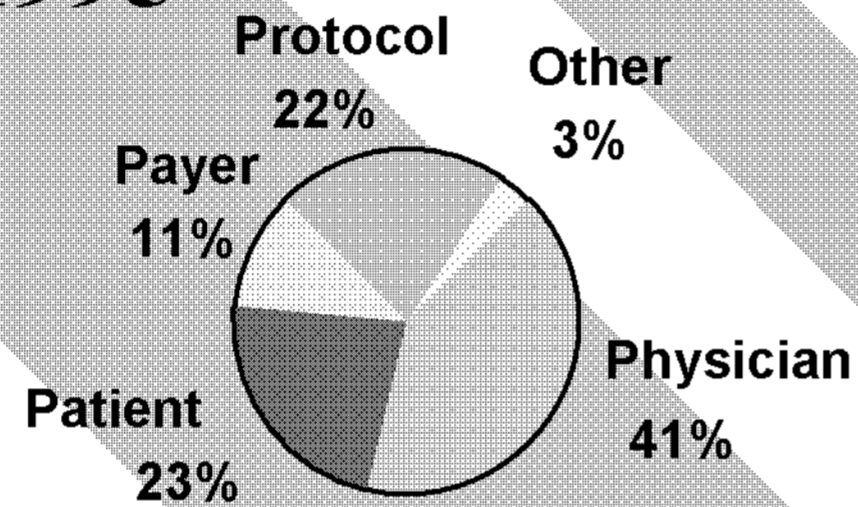
**US - 1995**



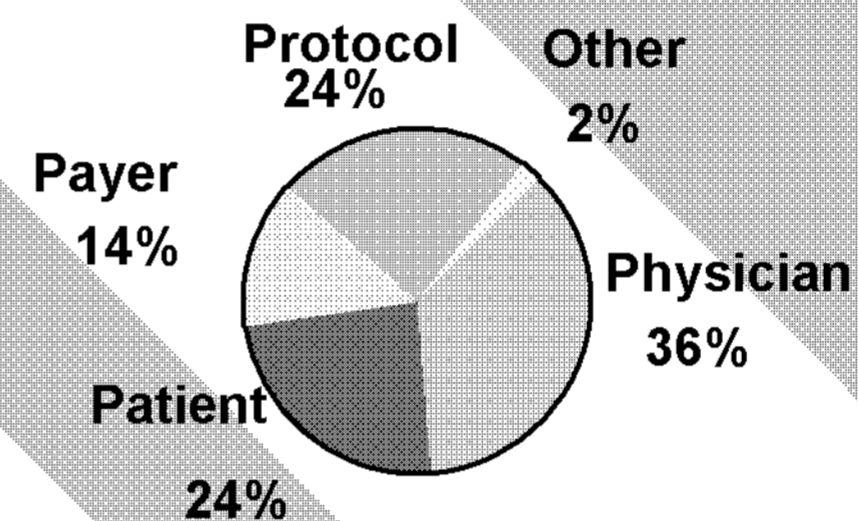
**US - 2000**



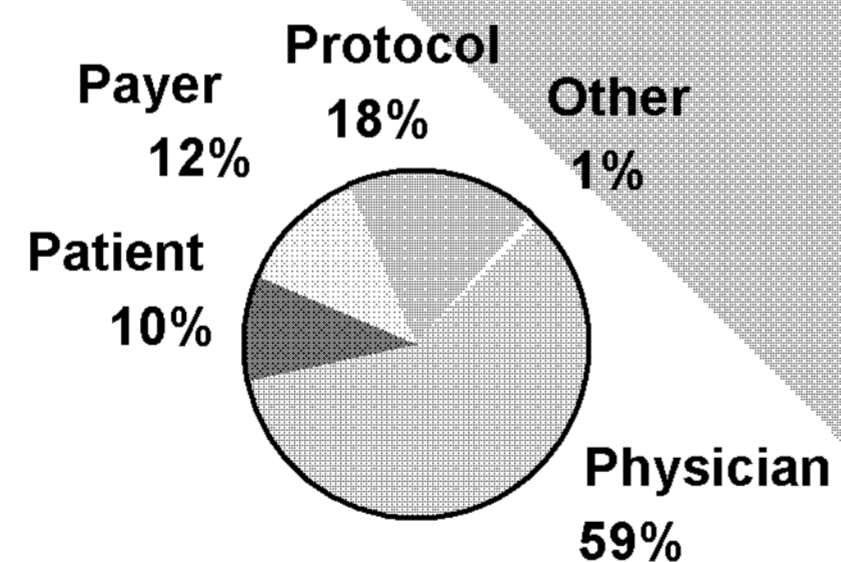
**UK - 1995**



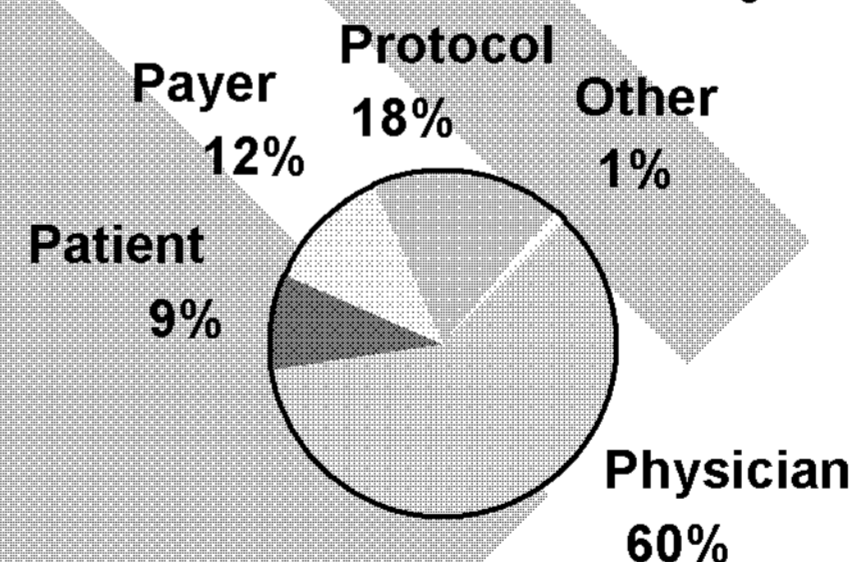
**UK - 2000**



**Italy - 1995**



**Italy - 2000**



- Predict an increase in the influence of payers and treatment protocols (i.e., treatment algorithms) in both the United States and the United Kingdom, and the diminished relative power of physicians, as well as an erosion of patient influence in the US market.
- In contrast, the relative influence of players in Italy is not projected to change with the physician continuing to enjoy a influence.

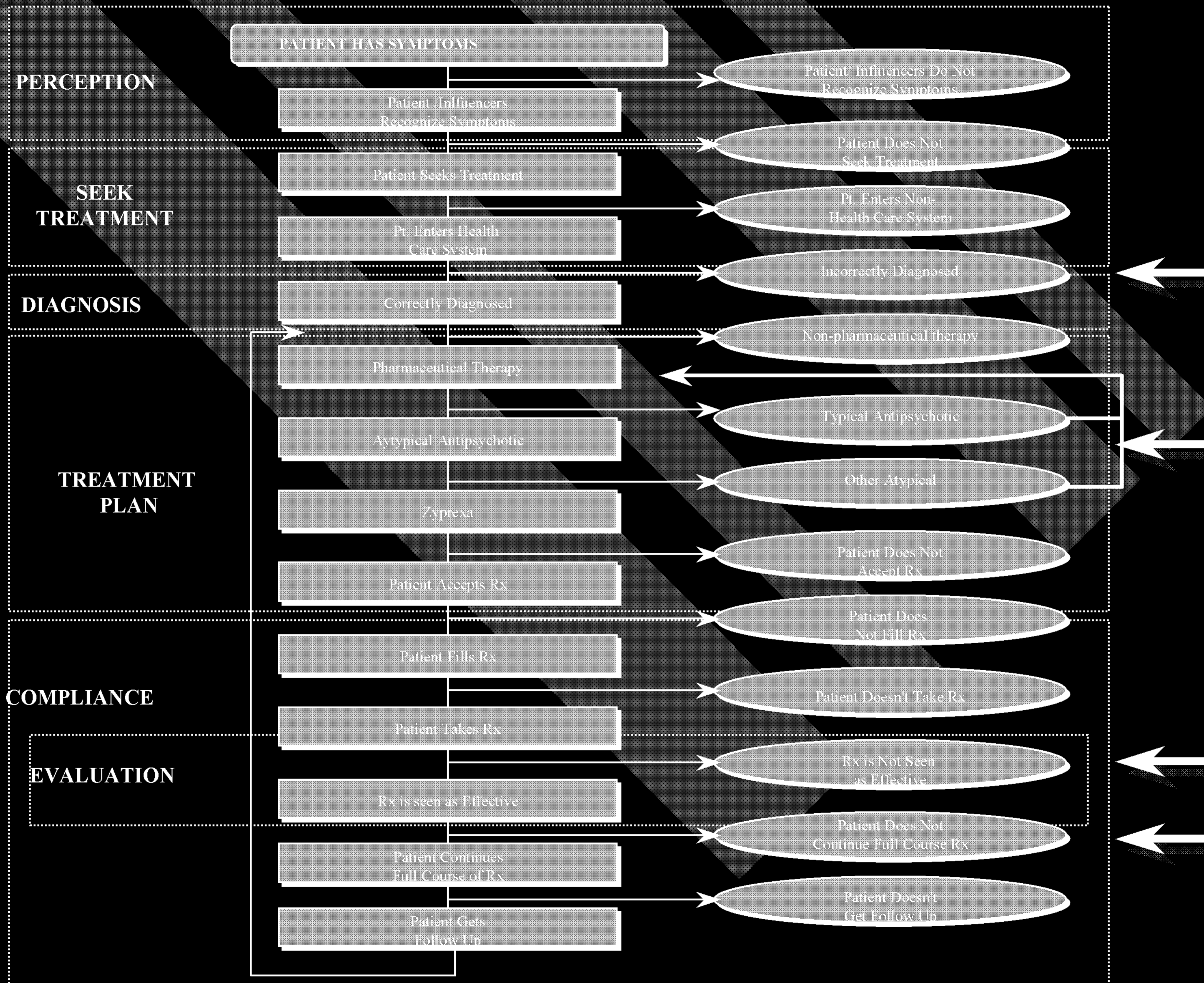
Source: Global Healthcare Associates, Inc., 1995

# Healthcare Transaction Model

The primary goals of this model are to:

1. Identify where value is lost: identify where a potential Zyprexa patient would not receive treatment.
2. Identify the primary and secondary players involved in the transaction
3. Identify the primary reasons a patient did not receive treatment
4. Identify levers for the areas of greatest loss: List suggestions that can be used to expand the demand for Zyprexa.

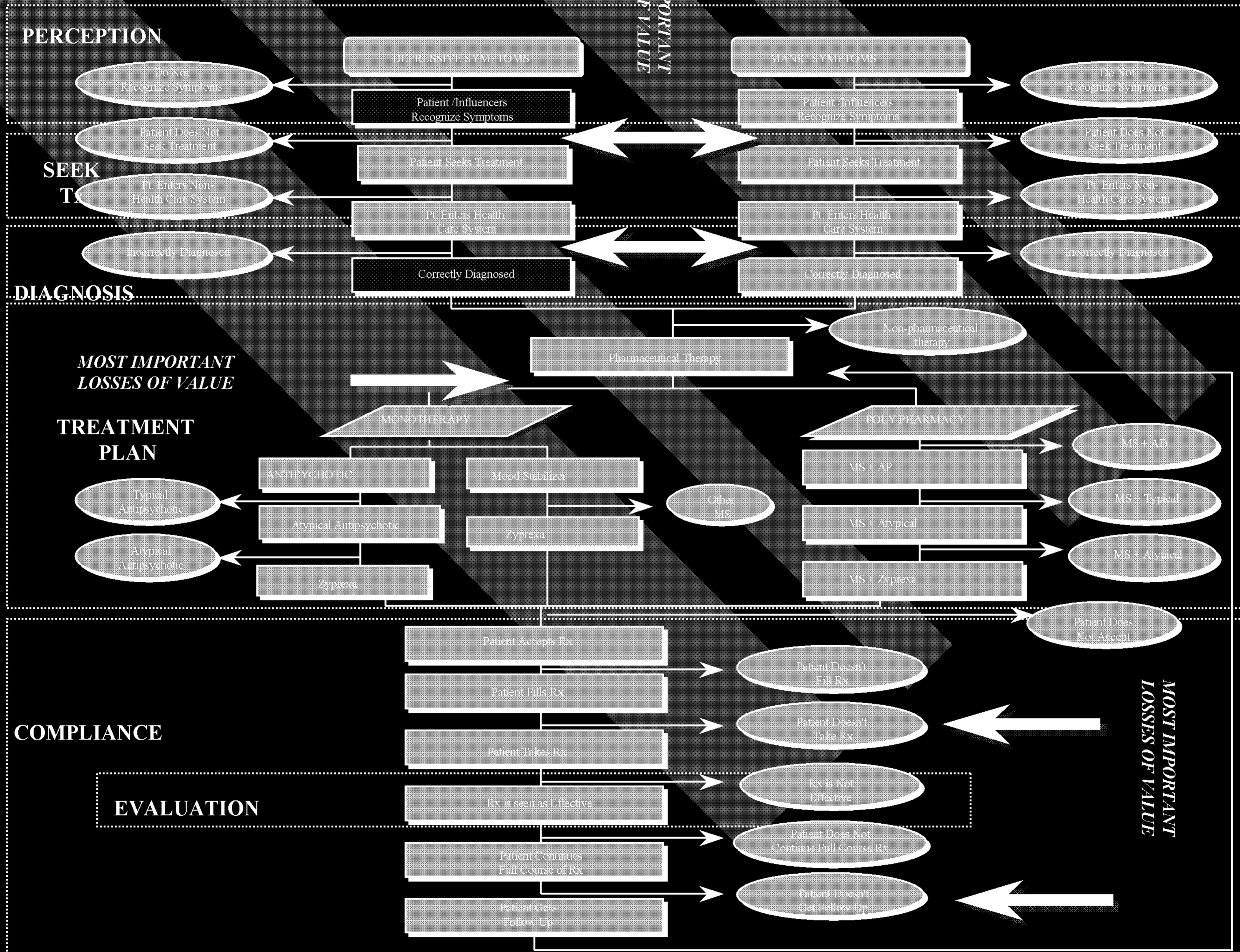
# Schizophrenia Transaction Model



**MOST IMPORTANT LOSSES OF VALUE**

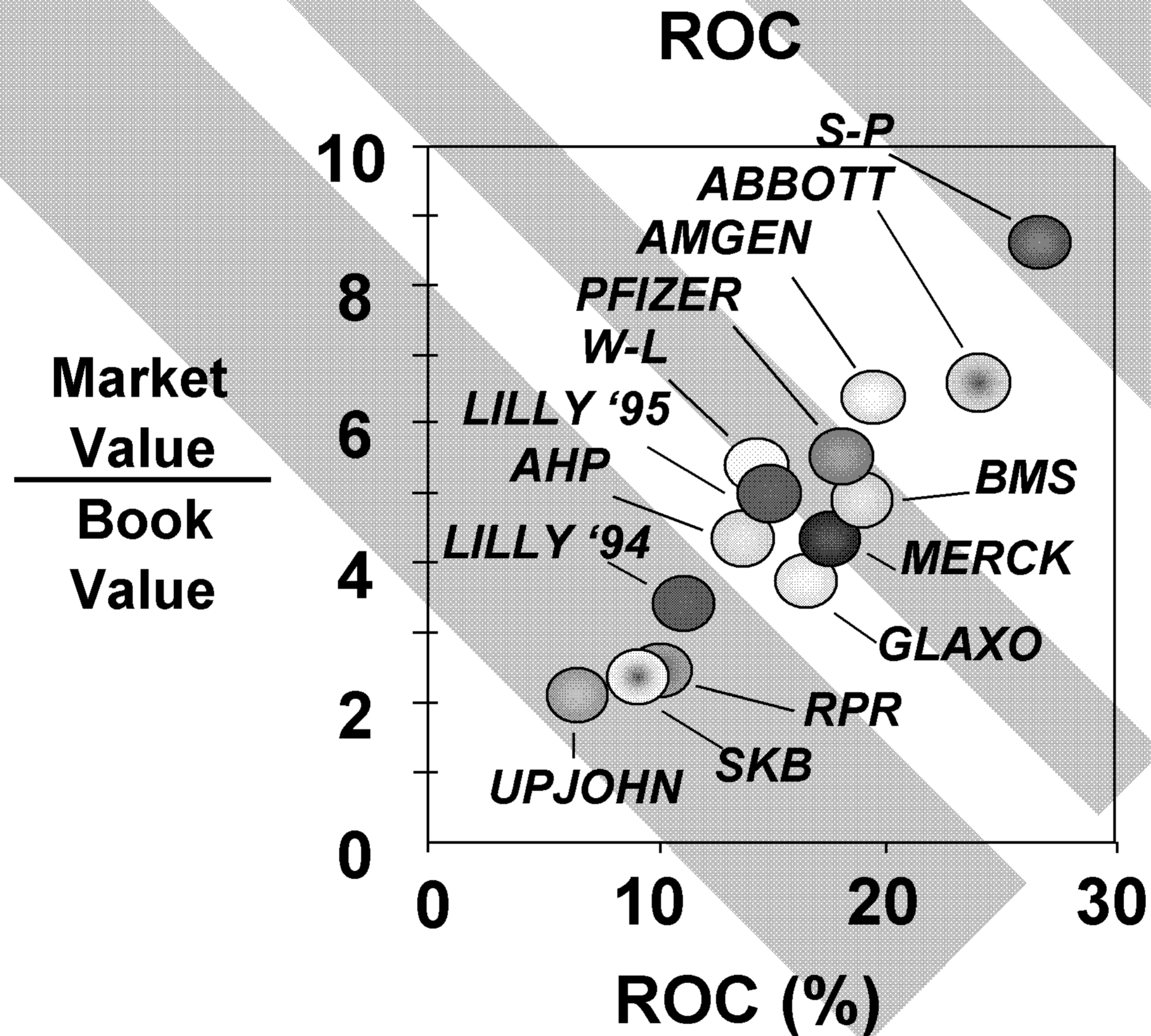


# Bipolar Disorder Transaction Model



# Business Fundamentals

## Drivers of Market Value of Pharmaceutical Companies



- **Most neuroscience ventures are highly ROC positive**

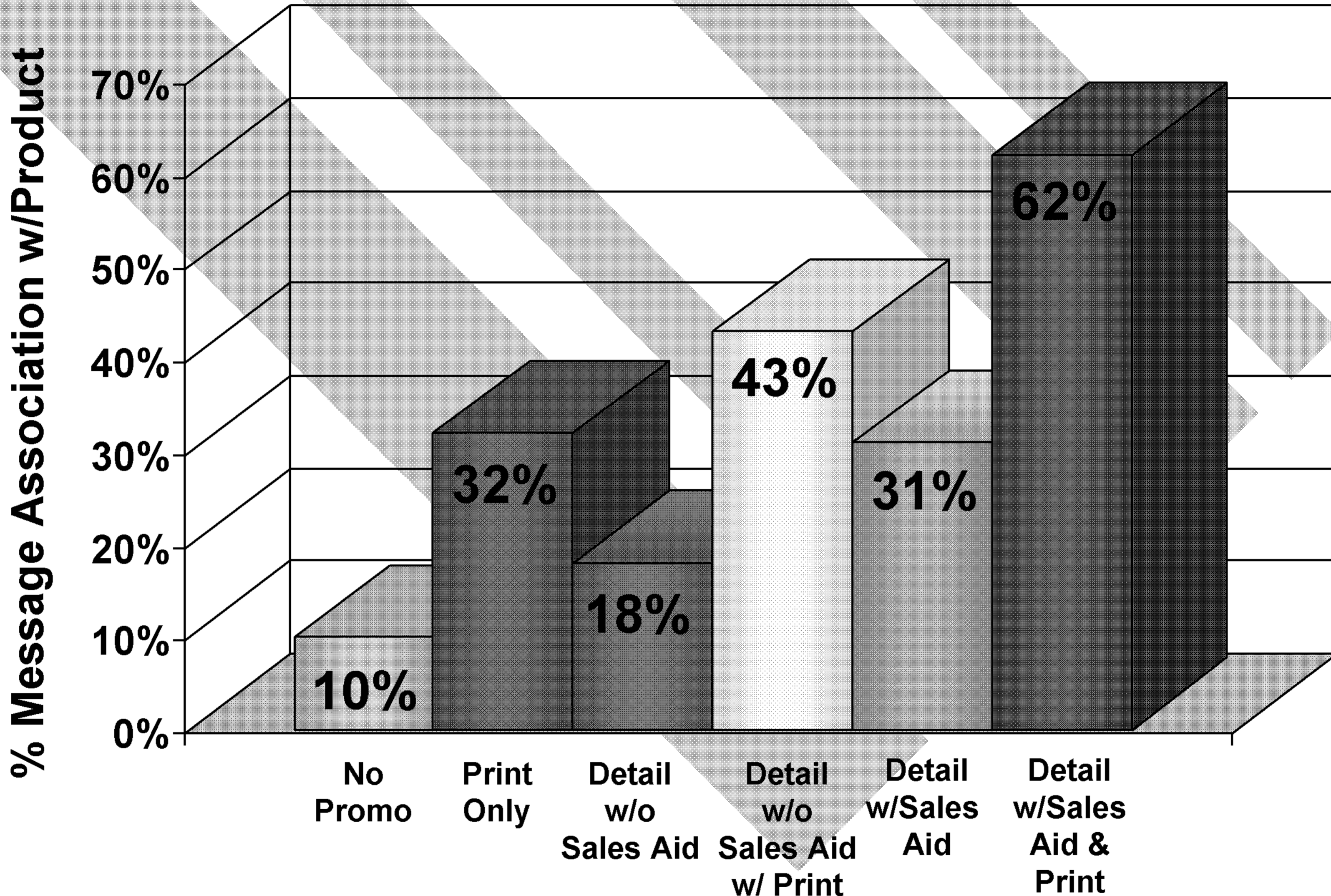
# *Value Cycle Activities and Drivers of Value*

- Demand Creation activities are resourced principally from operating expense (OPEX). OPEX drive incremental demand for our products (SOM).
- For Lilly Neuroscience, as long as each incremental \$1.00 invested in OPEX produces \$1.10 in sales, increase NOPAT.
- Currently, Lilly Neuroscience is generating about \$5.00 in sales for every \$1.00 in OPEX globally. There is significant upside for Lilly if OPEX are optimized, ie, drive additional sales and NOPAT.

# What activities drive SOM?

- The inherent characteristics of the molecule itself
- The accumulated selling and marketing activities invested in a product over time
- The current selling and marketing activities invested in the product

# *Effect of Combining Promotional Tools*



Source: HCI, Inc.

## Effect of Combining Promotional Tools — Contd.

- An audit of total non-sales force promotional spending by pharmaceutical companies in the United States during 1996 ranks Lilly 24th in total non-personal spending, versus 5th for Pfizer, 9th for Zeneca, 14th for Pfizer's Roerig, 15th for Janssen, and 19th for Abbott.
- None of Lilly's products were in the top 25 non-detail promotions in the United States in 1996. Prozac's chief competitors Zoloft and Paxil were ranked 7th and 16th respectively.

# COMPETITOR ANALYSIS: Product profiles

<i>Profile:</i>	<i>ziprasidone</i>	<i>quetiapine</i>	<i>sertindole</i>	<i>risperidone</i>
Submission Approval	3/97 Q1-Q2 '98	8/96 Approvable letter 7/97US Approved UK 8/4/97	10/95 7/96 (UK), Austria, Denmark, and Netherlands	8/93 2/94, (50+ countries)
Patent expiration	2008	2006	2010	2008
Class	N5AA	N5AA	N5AA	N5AA
Receptor affinity	5HT2, D2, D1, D4	5HT2, D2, D1	5HT2, D2, A-1	5HT2, D2
Formulations	Tablets/SAIM	Tablets	Tablets	Tablets, liquid
Dose	BID	BID	BID	BID
Effective dose range	20-40mg	150-750mg	12-24mg	2-16mg
Optimum dose	20mg	300mg/day	20mg	4-6mg

# COMPETITOR ANALYSIS: Product profiles — Contd.

<i>Product:</i>	<i>Strength:</i>	<i>Weakness:</i>
<b>ziprasidone/Zeldox</b>	<ul style="list-style-type: none"> <li>-Different mechanism</li> <li>-Efficacy in +/- symptoms (*)</li> <li>-Superior efficacy in comorbid depression</li> <li>-No liver/blood problems</li> <li>- Less weight gain</li> <li>-Low EPS</li> </ul>	<ul style="list-style-type: none"> <li>-BID</li> <li>-Must take w/ food</li> <li>-Increased prolactin levels</li> <li>- Weight gain</li> <li>-Agitation / Somnolence or postural hypotension</li> </ul>
<b>quetiapine/Seroquel</b>	<ul style="list-style-type: none"> <li>-Efficacy in +/- symptoms*</li> <li>-Low prolactin increase</li> <li>-Low level EPS</li> <li>-Safety profile</li> </ul>	<ul style="list-style-type: none"> <li>-Lack of robust efficacy (questionable in negative)</li> <li>-BID / Dose titration postural hypotension</li> <li>-Efficacy comparable to haloperidol / chlorpromazine</li> <li>-Agitation-dose related/ weight gain</li> </ul>
<b>sertindole/Serlect</b>	<ul style="list-style-type: none"> <li>-Efficacy in +/- symptoms*</li> <li>-Placebo level EPS</li> <li>-Prolactin levels within normal levels</li> <li>-Improvement in cognitive function</li> </ul>	<ul style="list-style-type: none"> <li>-QTc prolongation/mandatory ECG</li> <li>-Sexual dysfunction-low ejaculatory volume</li> <li>-Nasal congestion 30-40% of pts.</li> <li>-Long titration period</li> <li>-Postural hypotension</li> </ul>
<b>Risperdal/Risperidal</b>	<ul style="list-style-type: none"> <li>-Efficacy in +/- symptoms*</li> <li>-Experience (strength or weakness?)</li> <li>-No lab monitoring</li> <li>-Experience in other indications</li> </ul>	<ul style="list-style-type: none"> <li>-Efficacy in negative Sx questionable</li> <li>-EPS dose related</li> <li>-BID- titration</li> <li>-Tachycardia / rhinitis / agitation</li> <li>-Reports of : NMS / QTc prolongation</li> </ul>

\* relative to placebo



# **COLUMN II: Strategic Ends**

**I. Strategic Intent & Vision**

**II. Goals, Metrics, & Targets**



# Strategic Intent:

Zyprexa will be the world's number one neuroscience pharmaceutical in history.

# **Vision:**

- Our purpose is to create and deliver superior pharmaceutical-based health care solutions
- Selected disease state focus to maximize the product life cycle value
- Differentiations on safety efficacy, ease of use, and value
- Blunt the competition through a proactive, focused strategy effectively implemented by our internal partners
- Disease management where it increases value for Zyprexa in the HCT model
- Global focus / brand management
- Maintain an aligned organization characterized by talent, innovation, and dedication

# Zyprexa Launch Order

**CONFIDENTIAL**

EU Approval - Sep. 27, 1996

US Approval - Sep. 30, 1996

84 submissions

52 approvals

37 launches

(14 more - '97)

Austria  
Canada  
Denmark  
Finland  
Germany  
Netherlands  
Sweden  
United Kingdom  
United States

Australia  
Brazil  
Israel  
Romania

Greece  
Norway

Estonia  
Hong Kong  
S. Africa

Spain

Argentina

Columbia  
Malta  
Peru  
Philippines

Costa Rica  
Guatemala  
Mexico  
Portugal

Bulgaria  
Egypt  
Switzerland  
Venezuela

[Bahrain]  
Cyprus  
Haiti  
Khazakstan  
Lithuania  
Oman  
Panama  
Russia  
Slovenia  
[Venezuela]

[Chile]  
Luxembourg  
Morocco  
New Zealand  
Paraguay  
Syria  
[Yugoslavia]

Domin. Rep.  
Latvia  
Lebanon  
Indonesia  
Trinidad  
Tobago

Czech  
El Salvador  
Honduras  
Greece  
[Kuwait]  
[Oman]  
Pakistan  
Palestine  
Poland  
Singapore

Aruba  
[Croatia]  
Curacao  
Hungary\*  
Jamaica  
Nicaragua  
[Qatar]  
[UAE]  
Uruguay  
Yemen

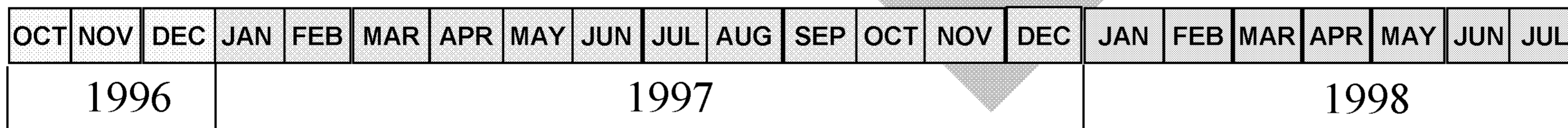
Macedonia  
Malaysia  
Tunisia

Belgium  
Botswana  
Zimbabwe

China  
Ecuador  
France  
Italy  
Ukraine  
Vietnam

Slovak Rep.  
Turkey

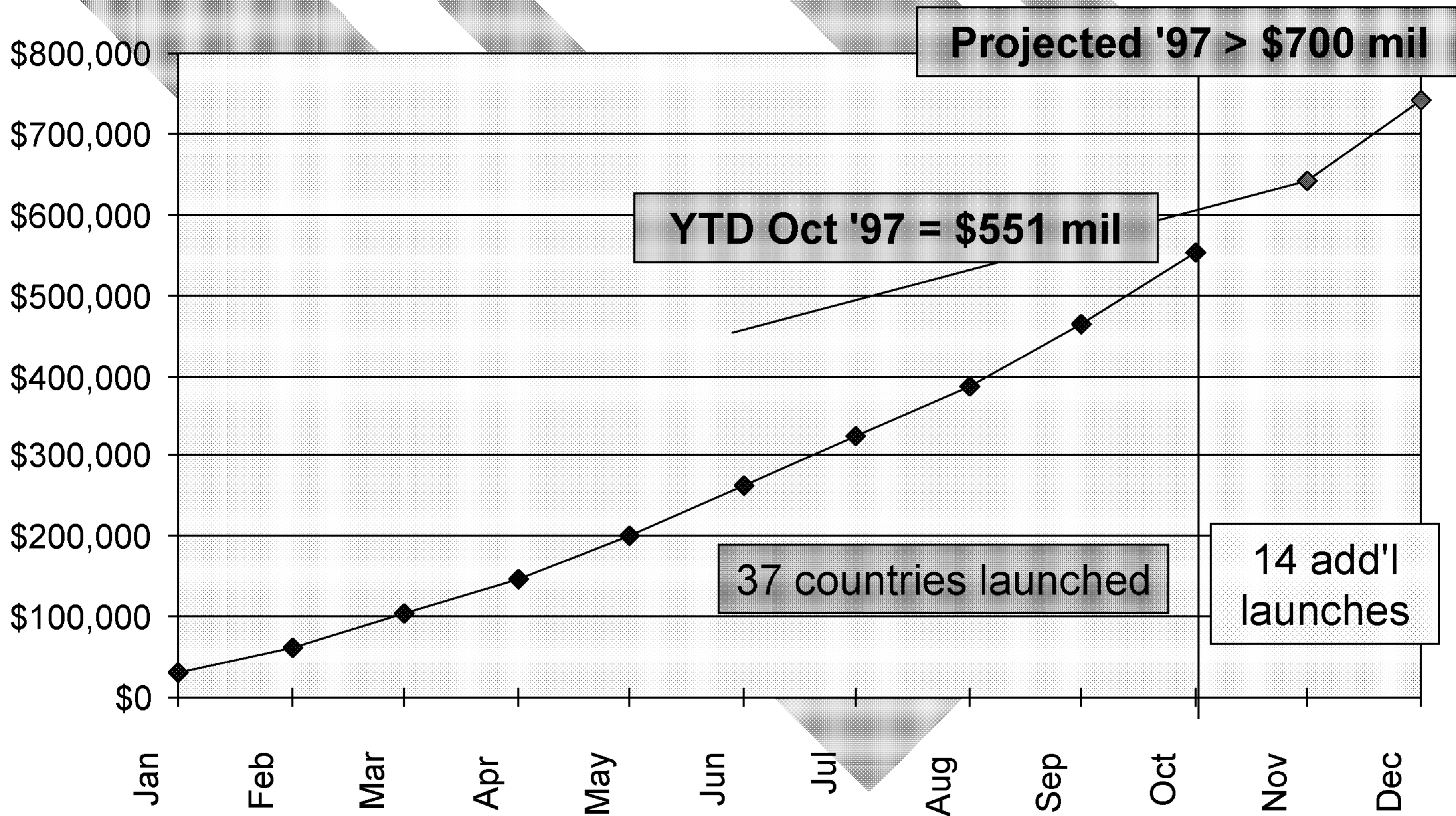
Kenya Oct '98  
[Saudi Arabia Oct '98]  
Thailand Nov '98  
Korea Mar '99  
Taiwan Apr '99  
Jordan Jul '99  
Japan Q3 '01



KEY: Submission completed  
[ ] Special License Agreement

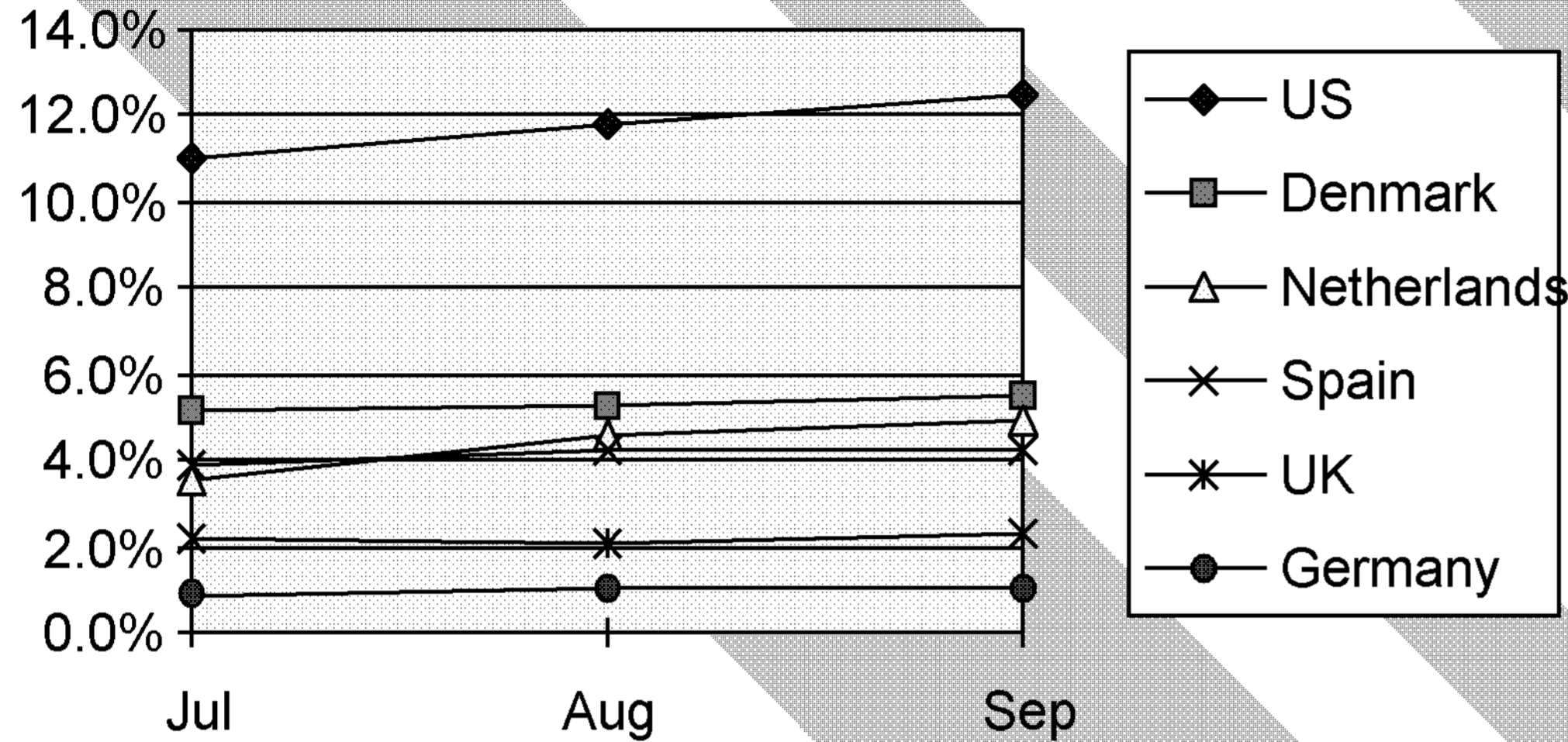
Approved! (Location indicates launch date)  
\* In current month indicates launch still expected

# Zyprexa YTD/Projected Global Sales



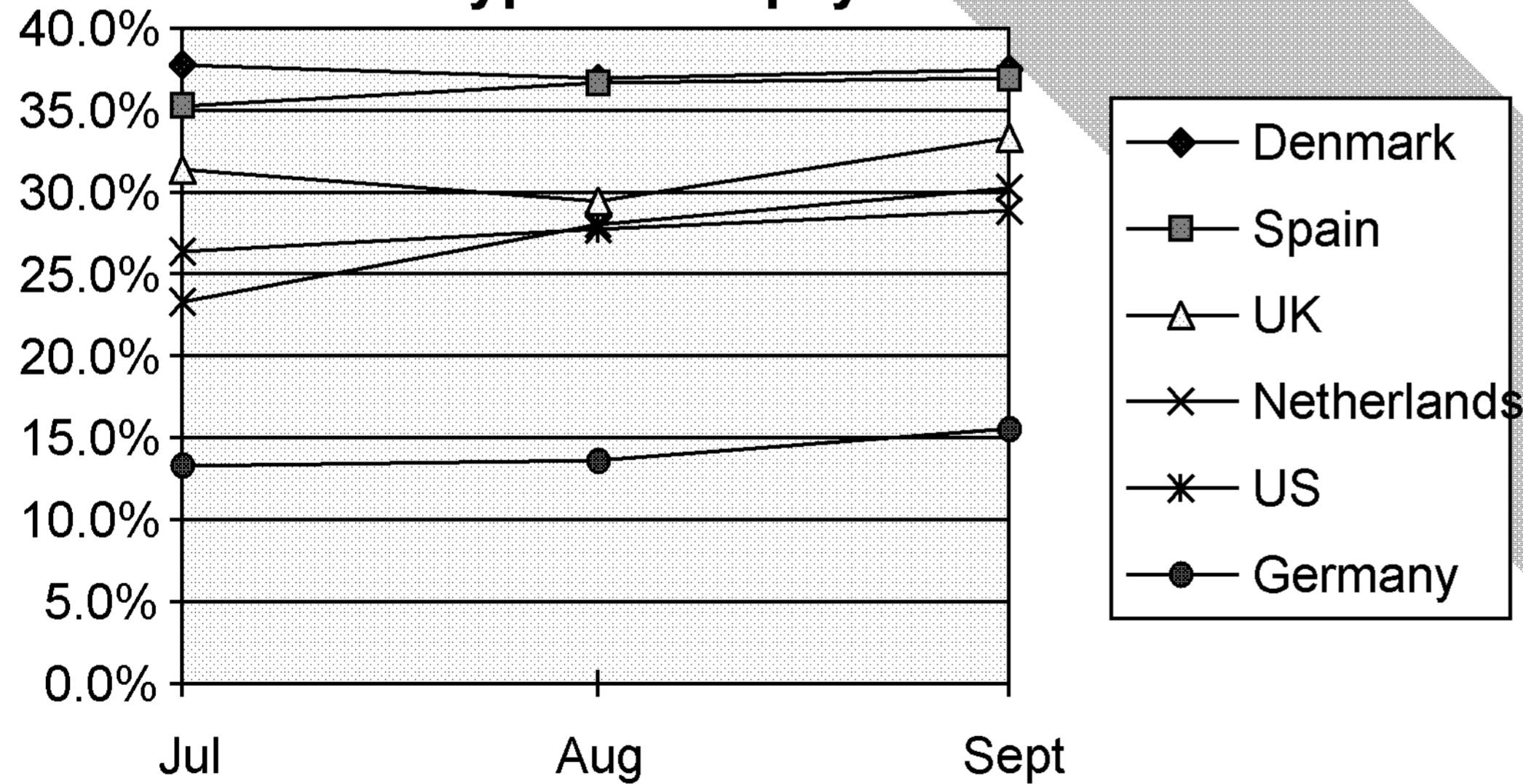
# Zyprexa Q3 '97 SOM Uptake

Share of Total N5A



- Adoption of atypicals in US far exceeds that of Europe.
- Share of total N5A will therefore show US far ahead of other launches

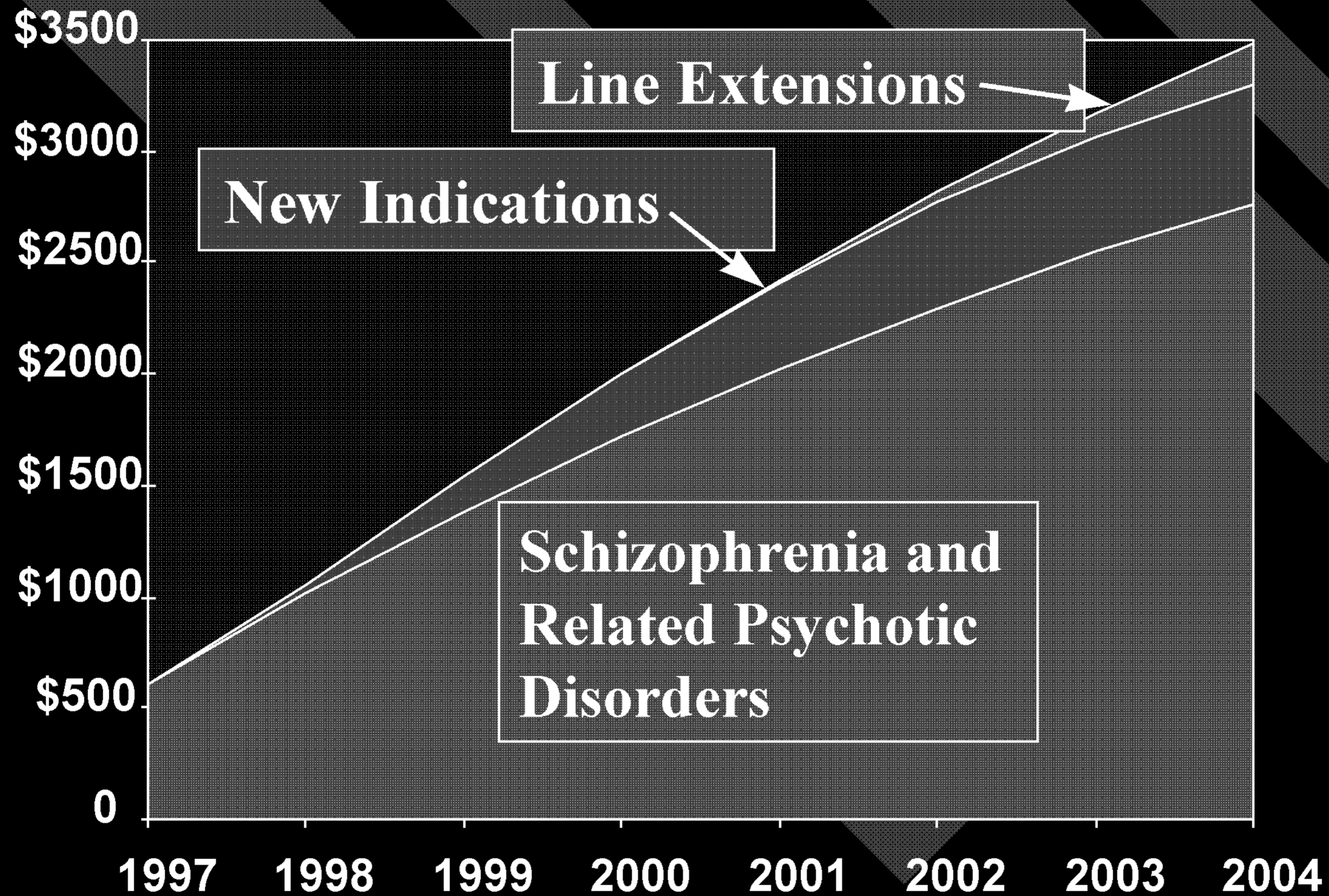
Share of Atypical Antipsychotics



- However, European affiliates showing good uptake vs. other atypicals (w/ exception of Germany)
- Challenge: Accelerate adoption of atypicals in Europe

# Zyprexa Sales: Long Range Forecast

Annual sales (000)



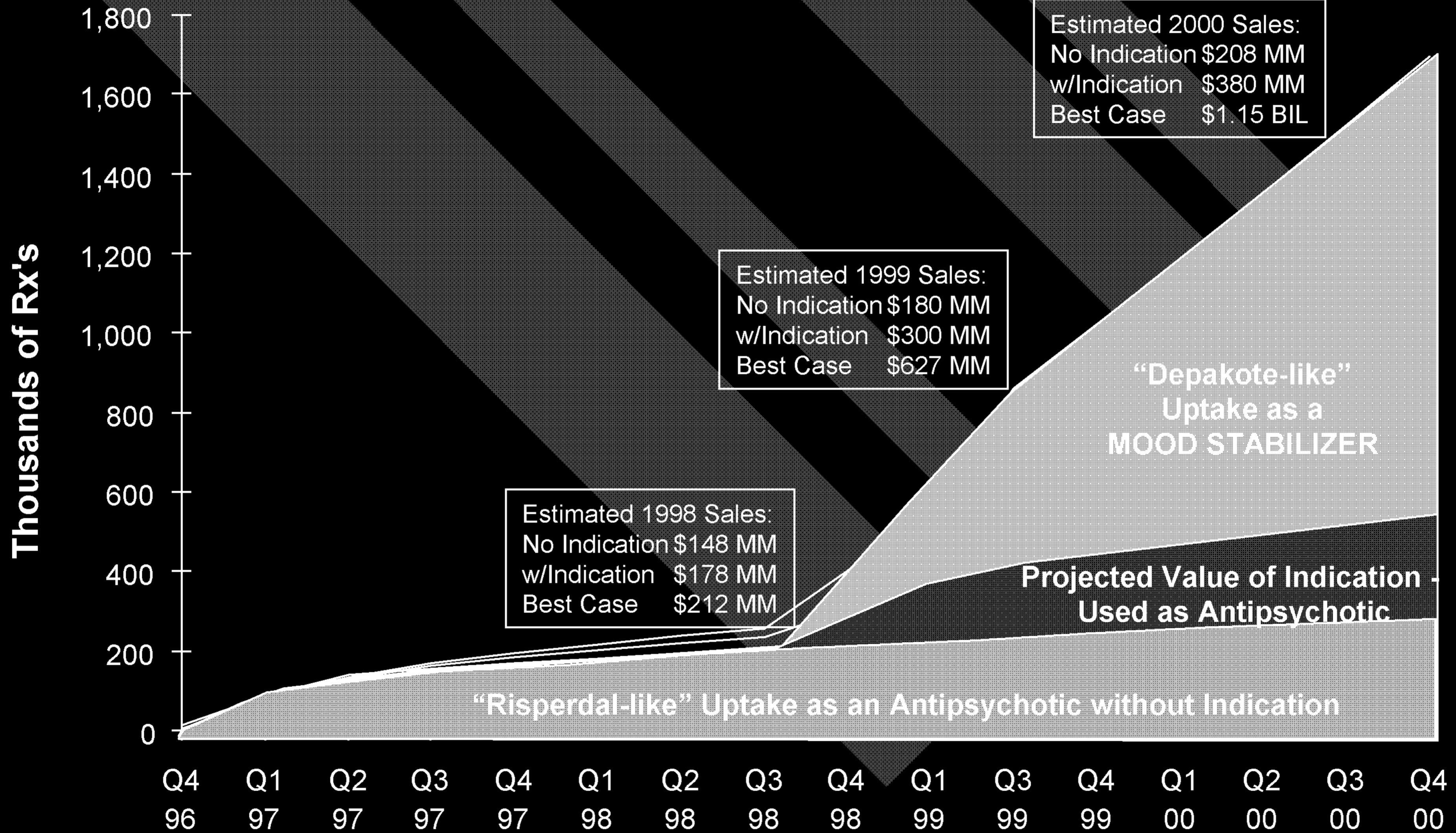
**•We cannot afford to be complacent!**

# Zyprexa Pricing Update

	10 mg @ Spot rate	10 mg @ 9/96 rate		Premium vs. 6 mg
	\$ 6.64	\$ 6.64		
	\$ 5.73	\$ 6.60	-13.2%	
	\$ 5.47	\$ 6.01	-8.9%	
	\$ 5.44	\$ 5.13	5.9%	
	\$ 4.86	\$ 4.93	-1.5%	
	\$ 4.86			
	\$ 4.84	\$ 5.26	-8.1%	-21%
	\$ 4.79	\$ 5.23	-8.6%	23%
	\$ 4.75	\$ 4.75		
	\$ 4.61	\$ 5.33	-13.5%	
	\$ 4.57	\$ 5.33	-14.3%	
	\$ 4.53	\$ 5.29	-14.3%	4%
	\$ 4.17	\$ 4.87	-14.4%	5%
	\$ 4.09	\$ 4.79	-14.6%	0%
	\$ 4.07	\$ 4.76	-14.7%	7%
	\$ 4.06	\$ 4.73	-14.8%	1%
	\$ 4.07	\$ 4.63	-12.7%	22%
	\$ 3.72	\$ 4.29	-13.3%	



# Global Zyprexa Bipolar Forecast





# **COLUMN III: Strategic Means**

- I. Assess Organizational Structure**
- II. Assess Capabilities**
- III. Product Strategy**

# Zyprexa Product Team

**Core Team**

<b>G. Tollefson - Team Leader</b>	<b>A. Webber - Regulatory Coordinator</b>
<b>V. Rampey - Director of Operations</b>	<b>D. Lynch - Manager of CM&amp;C</b>
<b>J. Lancaster - Director of Marketing</b>	<b>J. Kaiser - Director of Market Research</b>
<b>A.M. Crawford - Manager of Data Management</b>	<b>TBD - Japan Project Manager</b>

**Franchise Team**

- \* Krueger
- \* Breier
- \* Schmid

**Venture Team**

- \* Graffeo
- \* Sanger

**Customer Response Team**

- \* Crawford
- \* Ramsey

**Affective Disorder Team**

- \* Tohen

\* Sub-Team Leaders and Members of Core Team

# Capabilities

## Strengths

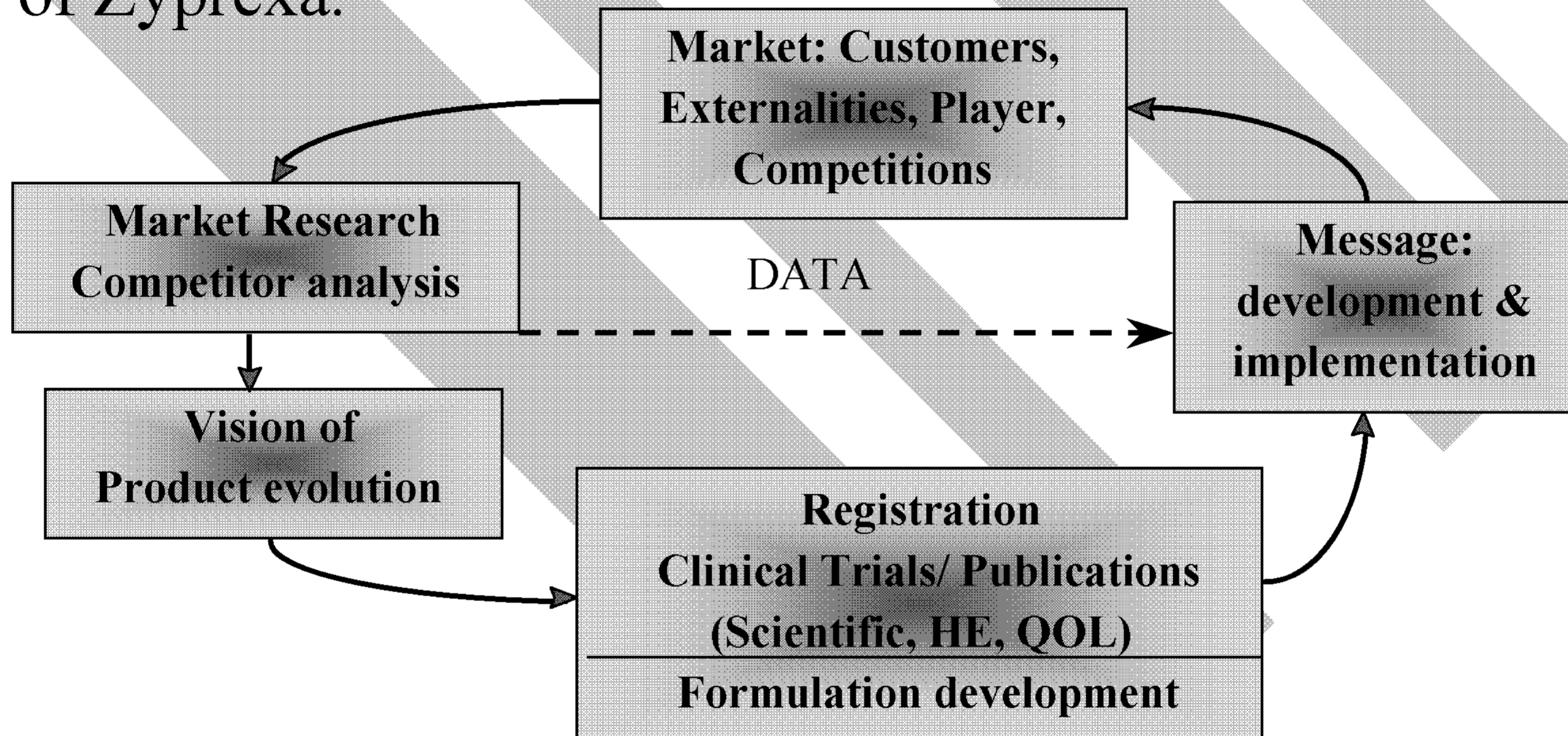
- Core message development
- Branding
- Publications Strategy
- Presentations
- Long term product strategy

## Opportunities to further upgrade

- Competitive analysis
- Market research
- Customer relations
- Communications
- HE / DSM
- Line Extensions

# I. Vision of the Value Cycle

- The Value cycle is defined as the list of all the activities that should be conducted in the areas of discovery, development, demand creation and sourcing in order to optimize the value of Zyprexa.



**Manufacturing / Sourcing**

**Distribution Strategy**

**Pricing**

**Accessibility (Formularies, Government Reimbursement...)**

- **Current Message**

At launch, Zyprexa was positioned as a first line anti-psychotic for a broad spectrum of patients because it offered the best combination of efficacy, safety and tolerability and could result in optimal economical value for patients.

- **Evolution of the Message**

- Zyprexa as a unique molecule

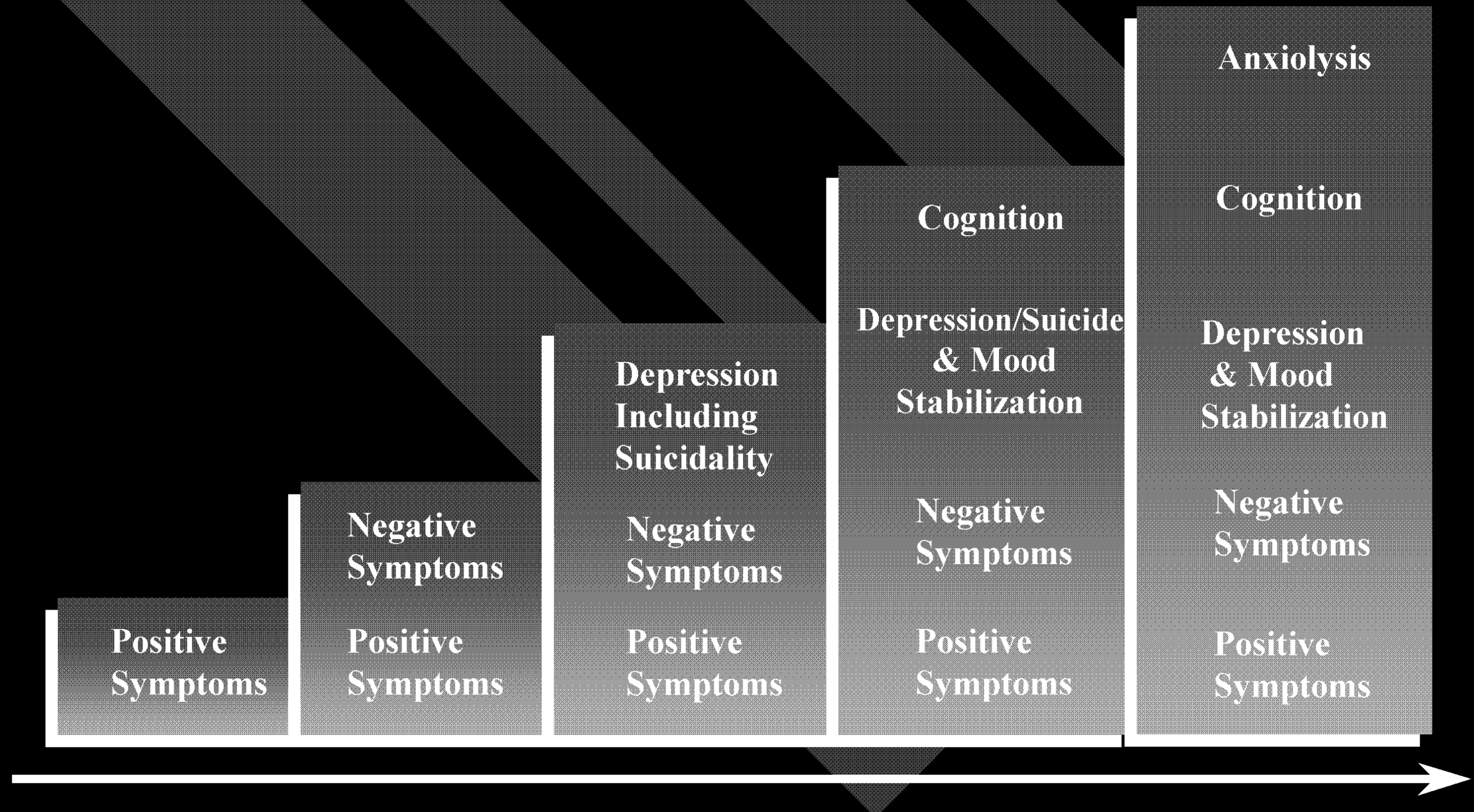
- Positive differentiation of Zyprexa by the customer — desirable product attributes

- ex: broad spectrum efficacy with a superior safety profile

- Enhance perception of Zyprexa as a first choice earlier in the course of illness

- The combination of pleiotropic pharmacology & a high degree of safety establish Zyprexa's potential in other disorders

# Improved Control of Symptoms of Schizophrenia





## **Bipolar Vision of Product Evolution**

To be a leader in the bipolar market, Zyprexa will need to be viewed as *true mood stabilizer*. A *true mood stabilizer* will work in acute manic episodes without inducing depression, acute bipolar depression without inducing mania, and protect the patient from future episodes of mania or depression.

### STRENGTHS

- Efficacy in manic & psychotic symptoms of an acute manic or mixed episode
- Efficacy in rapid cycling bipolar patients
- Efficacy in depressive symptoms in patients with non-affective psychosis
- Excellent safety profile - toxicity, drug interactions)
- QD dosing & no titration for most patients
- Only antipsychotic w/ an indication for bipolar

### WEAKNESSES

- Weight gain
- Higher cost (esp. vs. Lithium/Depakote)
- Only acute mania data/indication @ launch. Lack of maintenance or depression data
- No injectable form available at launch
- Lack of comparative data (lithium, haloperidol, Depakote)

### OPPORTUNITIES

- Unsatisfied market - Huge potential for increase in sales/value to Zyprexa & Lilly
- Chance to further boost the brand
- Capitalize on the success in treating psychosis
- Leverage psychosis sales w/ a 2nd indication and proven efficacy in an mood disorder.
- 1st antipsychotic to bipolar market - opportunity to further blunt the competition
- Change the bipolar treatment paradigm
- ROC

### THREATS

- New atypicals riding Zyprexa coat tails.
- Not currently perceived as a mood stabilizer or a candidate for first-line treatment of bipolar disorder
- Increased number of competitors
  - anticonvulsants & atypicals
- Increased price competition restrictive formularies

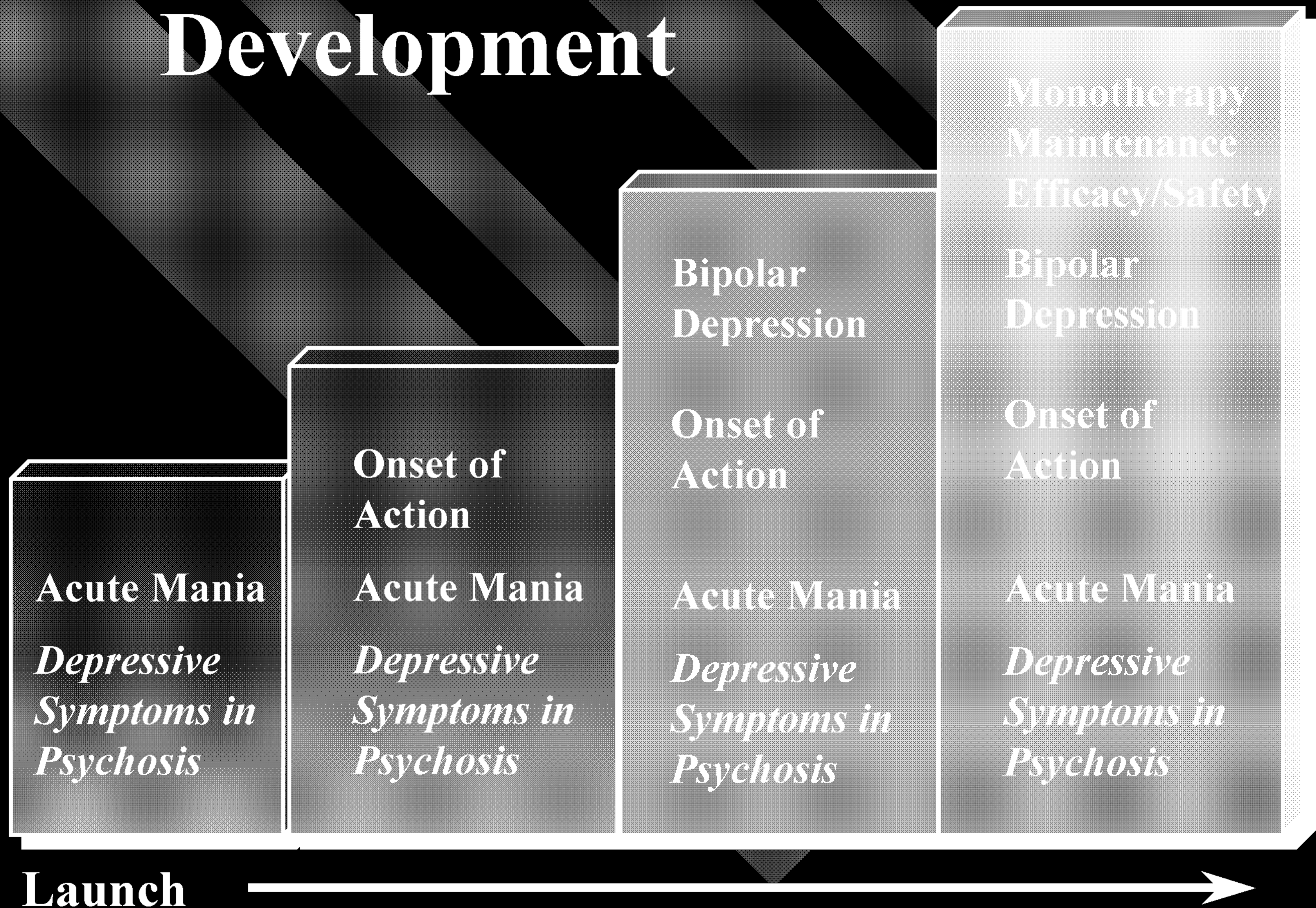
# Competitive Message Analysis

Key Criteria	Zyprexa	Lithium	Depakote	Carbam azepine	Haldol	Risperidal	SSRIs
<b>EFFFICACY</b>							
Acute Mania	+++	++	+++	++	++	+	-
Acute Depression	+	+	-	-	-	ND	++
Maintenance	ND	+	+	+	ND	ND	ND
Doesn't Induce Change of Polarity	++	++	++	++	--	+	--
<b>SAFETY</b>							
Blood Monitoring	+++	--	-	---	+++	+++	+++
Drug Interactions	+++	--	+	---	+	+	+
TD	+++	+++	+++	+++	---	-	+++
Toxicity	+++	---	-	-	++	+++	+++
<b>PATIENT ACCEPTABILITY</b>							
Tolerability	+++	-	++	--	-	++	+++
Convenience (dose/titration)	+++	-	-	-	-	-	++
Monotherapy Acute Mania	++	+	++	--	-	ND	---
Weight Gain	---	--	--	+++	+	-	+++
EPS	+++	++	+++	+++	---	-	+++
Cost	---	+++	-	+++	+++	---	--

+++ = definitive evidence/advantage  
 ++ = strongly suggested  
 + = definitive evidence/advantage

ND = No Data  
 - = minor issue  
 - - = clinical concern/disadvantage

# Bipolar Message Development



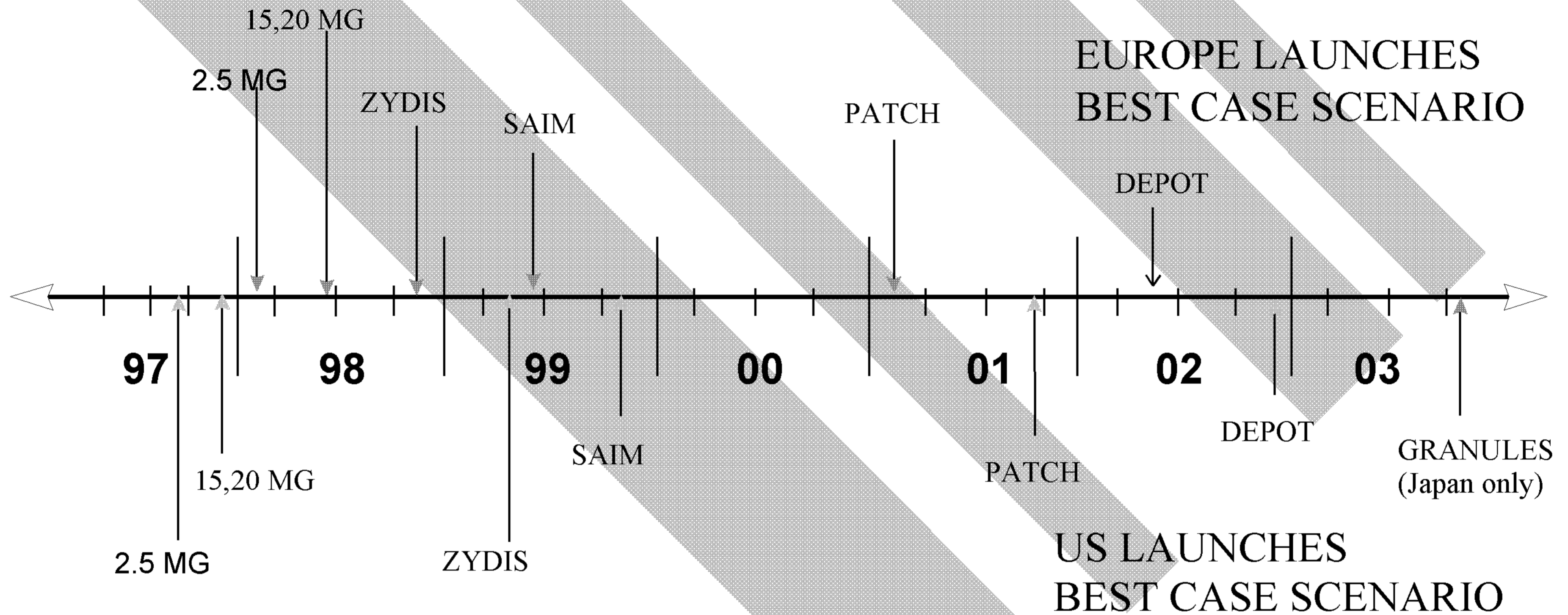
# Link '97 Studies to Value Propositions

	<b>Completed</b> <i>italic = accepted &amp;/or published</i>	<b>High Priority</b>	<b>Medium Priority</b>
<b>New Comparators</b>	<i>Olz vs Risperidone (Tran)</i> <i>Cloz Discontinuation (Tollefson)</i>	P022 (All measures vs Risp) HGBU (all measures vs Risp) Olz Vs Clozapine	
<b>Patient types</b>	Geriatrics from HGAJ (Tollefson) Partial responders Schizoaffctive (Tran) First Episode	Geriatrics from HGAJ (Tollefson) Partial responders Schizoaffctive (Tran) First Episode	Predominantly Sx Clozapine non responders Risperidone non responders
<b>Efficacy</b>	<i>DepressiveSx (Toll - Archives)</i> DepressiveSx vs Placebo Core negative SX. (Tollefson)	Olz vs Fluphenazine (Anxiety) PO22 Cognition (vs Hal & Risp) Psychobehavioral J schizo only (superioity +Sx)	
<b>Safety</b>	<i>Prolactin (AMC Schizo Res.)</i> <i>TD (Toll. - Am Journal)</i>	Weight Gain (Tollef brief report) Weight Gain (Kinon)	
<b>Switching</b>	Switching Clozapine		Hal outpatientswit. (HGEJ)Swit. no wash out (Germ)
<b>HealthEcon</b>	<i>HGAD QOL (HamiltonNeuro)</i> <i>HGAJ / HGBG model</i> HGAJ QOL HGAJ medicaressource use HGAJ Cost efficacy	HGBU HE & QOL vsisp HGBG cost vs risperidone HGBG QOL vs risperidone	Family / Care giver burden
<b>Long Term</b>	<i>Standard dose vplac in maintenance</i> Standard dose vs Hal imaint. (Tran) TD (Beasley - Archives)		

# 1998 Clinical Studies Plan

	97 Q4	Q1	19 Q2	98 Q3	Q4	Q1	19 Q2	99 Q3	Q4	Q1	20 Q2	00 Q3	Q4
<b>PATIENT TYPES</b>													
Prodromal Schizophrenia	oct												'01
Geriatrics (nursing Home)	dec			aug									
Geriatrics ( olz vs risp)					oct					Feb			
Tt refractory ( Lieberman)	nov						apr						
<b>NEW COMPARATORS</b>													
Ziprasidone head to head					oct					feb			
Quetiapine head to head (pending market uptake)			apr							jan			
<b>EFFICACY</b>													
Cognition/QOL (3 arms)			apr					aug				jun	
Depression and Anxiety				aug						feb			
<b>SAFETY</b>													
Weight Gain (Weiden)	dec			aug									
Prolactin		mar						sep					
<b>L. TERM OUTCOMES</b>													
Relapse Prevention	dec										may		
Health Econ (US-VA)		jan											dec
Health Economics (Europe SCAP)		mar											'03
<b>LINE EXTENSIONS</b>													
Short Acting IM					nov			sep					

# Line Extension Plan



**•15, 20 mg decisions awaiting Pfizer US pricing/French Zyprexa price**

# Communicate Product Information

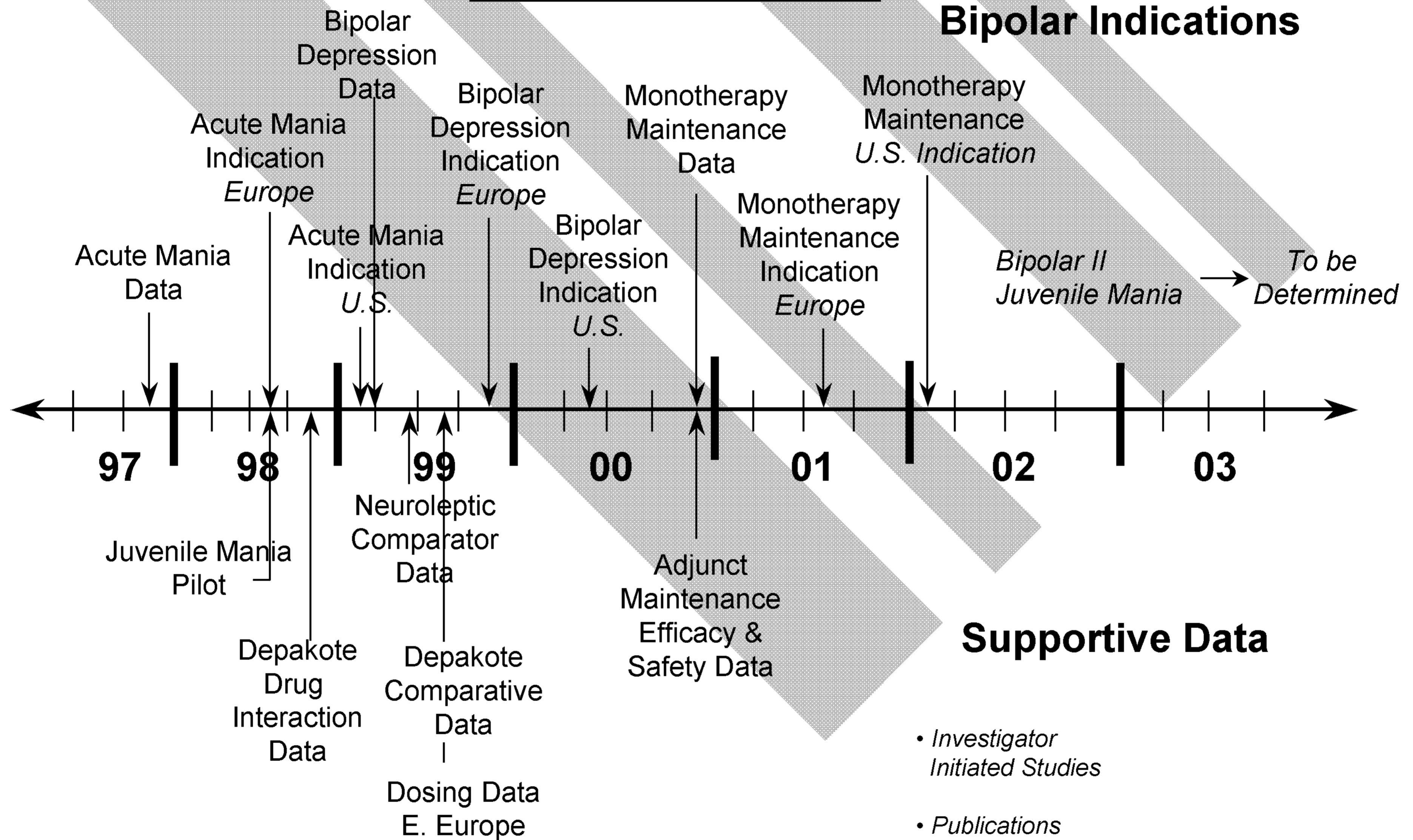
- Marketing Publications
- International Congresses
- Public Relations
- WPA campaign



# Affective Product Program

- Generate the Bipolar Data Needed

## Bipolar Data Timeline



# Communicating Data Results: Bipolar

## Bipolar Marketing Plans: Planned / Needed

1997	1998	1999	2000
<ul style="list-style-type: none"> <li>• <b>US, EUR &amp; LA Advisory Panels</b></li> <li>• <b>Symposia Strategy</b></li> <li>• Branding/Advertising Campaign</li> <li>• EUR Submission Press Events</li> <li>• <i>Publications Plan</i></li> <li>• <i>Launch Strategy</i></li> <li>• <i>LA &amp; AP BPD Advisory Panels</i></li> </ul>	<ul style="list-style-type: none"> <li>• <b>US, EUR &amp; LA Advisory Panels</b></li> <li>• BPD Screening at National Depression Screening Day (US)</li> <li>• BPD Sessions @ GMCs</li> <li>• Davos BPD Program</li> <li>• PR Programs (Journalist Prog, Grassroots Media &amp; Pubs)</li> <li>• Scientific Symposia (ECNP, APA, CINP, WPA Regionals)</li> <li>• NDMDA &amp; NAMI Grants</li> <li>• EUR Approval Press Events</li> <li>• US Submission Press Events</li> <li>• <i>Scientific Symposia (ANCP, NCDEU, AEP, ENS, EFNS, AAN)</i></li> <li>• <i>PR Backgrounder on Costs (Gellenberg)</i></li> <li>• <i>US/OUS BPD “ PsychLink”</i></li> <li>• <i>US Investigator Meetings</i></li> <li>• <i>Closed BPD Symposium</i></li> <li>• <i>AP Advisory Panel</i></li> <li>• <i>Patient Education Materials</i></li> <li>• <i>GAMIAN &amp; WFMH Advocacy Partnerships</i></li> <li>• <i>Rotary Club “Erasing the Stigma” Partnership</i></li> <li>• <i>WPA BPD Program</i></li> <li>• <i>GP/ Psych Nurse CME Programs</i></li> <li>• <i>BPD CME Programs</i></li> </ul>	<ul style="list-style-type: none"> <li>• <b>US, EUR &amp; LA Advisory Panels</b></li> <li>• US Approval Press Events</li> <li>• <i>US/OUS BPD “ PsychLink”</i></li> <li>• <i>DTC Exploration/Feasibility</i></li> <li>• <i>Living with BPD Newsletter</i></li> <li>• <i>Patient Retention Programs</i></li> <li>• <i>Caregiver/Payer Education Program</i></li> <li>• <i>BPD Sessions @ GMCs</i></li> <li>• <i>Scientific Symposia ( Intl Conf on BPD, ECNP, APA, ACNP, NCDEU, WPA Regionals, AEP, ENS, EFNS, AAN)</i></li> <li>• <i>EUR &amp; US Investigator Meetings</i></li> <li>• <i>Advocacy Group Partnerships</i></li> <li>• <i>WPA BPD Program</i></li> <li>• <i>European Journalist Briefings</i></li> <li>• <i>HCS/Disease Management Interventions (e.g., Patient Video)</i></li> <li>• <i>Celebrity Spokesman Campaign or Event Sponsorship</i></li> <li>• <i>HCS/Compliance Interventions</i></li> <li>• <i>Compliance Physician Education Programs</i></li> <li>• <i>Video Documentary on BPD</i></li> <li>• <i>ZYP BPD Global WWW Site</i></li> <li>• <i>AP Advisory Panel</i></li> </ul>	<ul style="list-style-type: none"> <li>• <b>US, EUR &amp; LA Advisory Panels</b></li> <li>• <i>US/OUS BPD “ PsychLink”</i></li> <li>• <i>Investigator Meetings</i></li> <li>• <i>Advocacy Group Partnerships</i></li> <li>• <i>WPA BPD Program</i></li> <li>• <i>BPD Sessions @ GMCs</i></li> <li>• <i>Scientific Symposia (CINP, ECNP, APA, ACNP, NCDEU, WPA Regionals, AEP, ENS, EFNS, AAN)</i></li> <li>• <i>HCS/Disease Management Interventions (e.g., Patient Video)</i></li> <li>• <i>HCS/Compliance Interventions</i></li> <li>• <i>Living with BPD Newsletter</i></li> <li>• <i>AP Advisory Panel</i></li> </ul>

# Venture Team: Generate the New Data Needed to Grow

Protocol	Description	Comparator	Type	Start Up Date	Last Patient Visit	Status
H G G M	Efficacy and Tolerability in Huntington Patients			1/15/98		
X 0 2 1 - B P	5 HT2 Receptor polymorphisms olanzapine treatment and sleep EEG			10/30/97		
H G D L	Tardive Dyskinesia Template: Italy	haloperidol	local (O U S) Template	12/10/96	11/12/97	Active
H G E R	Serotonin, Dopamine Interactions as a Target for Neuroleptic Drugs. (neuroendocrine study)		local (O U S) template	1/10/97	10/11/00	Active
H G F F	Olanzapine treatment of levodopa-induced dyskinesia in Parkinsonian Patients		local (O U S) template	10/1/97	10/3/98	Active
H G F P	Olanzapine treatment of Autism - pilot study		local (O U S) template	2/28/97	6/26/98	Active
→ V E N # 2	Psychosis in Alzheimers Disease	?	local (O U S) template	7/1/98		
A L Z # 2	Olanzapine in the treatment of Psychosis Associated Behavioral Disturbances in the Elderly with Dementia	placebo risperidone	new indication/label inclusion	6/15/98	6/11/99	In Plan
→ H G D H	First Episode Schizophrenia	haloperidol	New Indication/Label Inclusion	1/27/97		Active
H G E U	Olanzapine vs. placebo in the Treatment of Psychosis and Behavioral Disturbances Assoc. With Alzheimer's	placebo	New Indication/Label Inclusion	11/6/96	2/10/99	Active
H G F V	Treatment Associated Psychosis in Parkinson's Disease	placebo	New Indication/L a bel Inclusion	8/8/97	10/1/98	Active
→ H G G P	Olanzapine vs. Placebo for Treatment-Associated Psychosis in Patients with Parkinson's Disease		New Indication/Labeling	11/3/97		In Plan



# **COLUMN IV: Operational Plan**

**I. Resource Allocation**

**II. 1998 Business Plan**

# Dedicated Headcount Summary

	<b>97F</b>	<b>98Target</b>	<b>Original 98P</b>	<b>Rev. 98P</b>
<b>LRL</b>				
CM&C (MC50A)	5	5	4	4
Medical Plans (MC515)	44	47	53	47
Scientific Information (MC529)	18	21	33	25
Administrative (MC541)	13	13	14	14
<b>Sub-Total LRL</b>	<b>80</b>	<b>86</b>	<b>104</b>	<b>90</b>
Marketing	13	16	16	16
<b>Total Dedicated Team</b>	<b>93</b>	<b>102</b>	<b>120</b>	<b>106</b>

# Dedicated Expense Summary

(\$ Millions)	Original			Revised
	<u>97F</u>	<u>98P</u>	<u>98Target</u>	<u>98P</u>
<b>LRL</b>				
Comp. & Ben.	6.1	8.1	7.2	7.2
Other Expenses	13.3	13.5	12.0	14.6
Grants (Base Case)	15.0	15.6	20.9	15.6
Admin Objective				(1.4)
<b>Sub-Total LRL</b>	<b>34.4</b>	<b>37.2</b>	<b>39.2</b>	<b>36.0</b>
<b>GBU/Mktg. Expenses</b>	<u>6.8</u>	<u>11.7</u>	<u>6.4</u>	<u>8.6</u>
<b>Total Dedicated Team</b>	<b>41.2</b>	<b>48.9</b>	<b>45.6</b>	<b>44.6</b>

# Medical Grant Summary

	1998 <u>Base</u>	1998 <u>Challenge</u>
New Indications	\$7,854	\$12,162
Line Extensions	\$1,126	\$1,827
Schizophrenia	\$5,287	\$8,134
Exempt from IND	\$1,371	\$2,109
<b>Total Grants</b>	<b>\$15,638</b>	<b>\$24,232</b>

	1998 <u>Base</u>
<i>47 Studies Started before 1/1/98</i>	<i>\$9,314</i>
<i>16 Studies Started After 1/1/98</i> <i>(9 Clinical Pharmacology Studies)</i>	<i>\$4,953</i>
<i>Exempt Studies (Ongoing &amp; New)</i>	<i><u>\$1,371</u></i>
<i>Total 1998 Base</i>	<i>\$15,638</i>

# Summary

- We should take significant organizational pride in Zyprexa's success to date
- However, as the environment becomes increasingly competitive we must continue to work hard and together
- Zyprexa is a profound corporate opportunity
- Bipolar is an opportunity equal to our top NCE's. Can we launch and grow it properly in the face of redacted
- Alignment, communication, and effective implementation are essential