

OLANZAPINE

LifePlan

CONFIDENTIAL

July 1994

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Introduction

In July, 1993, a cross-functional multinational team was formed: charged with the development of a LifePlan for olanzapine. Throughout the ensuing year, this team devoted countless hours towards the completion of this document. During the development process, team members worked collaboratively with Corporate and affiliate project team members, and management around the world. The in-hand result is a working "road map" for the global development of olanzapine. Insofar as LifePlan is an ongoing process, this plan must be periodically re-examined and modified, if necessary, to ensure that we are focusing on and addressing the key driving forces facing us in our business.

Copies of this document should be handled in a confidential manner. Additional copies may be obtained from Jeff Kasher, J. R. Richards, or Gary Hadley.

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SECTION ONE

Background

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Background

LifePlan is a name derived from two terms -- lifecycle and planning. As evidenced by this name, LifePlan is focused on strategic planning over a product's entire lifecycle. The foundation of LifePlan is a process called "mapping."

"Mapping" is a term that describes many things. Its most basic meaning is that of the process a cartographer uses to develop maps of the Earth, its lands and motorways, etc. In its most conceptual form, *mapping* implies portraying the environment at a point in time. The term *mapping* that will be used in LifePlan describes a *process for developing, presenting, and communicating, across business functions, an understanding of the critical issues/choices facing the functions and the business.*

In every business, and for every product in the business, there are driving forces that define critical dimensions of competition. In the pharmaceutical business, these driving forces include differentiating your product, changing regulatory requirements, and the emergence of new markets. It is the goal of LifePlan to identify these critical issues and focus the strategic planning effort on the most critical issues. One of the key steps in determining where to focus involves the creation of LifePlan maps.

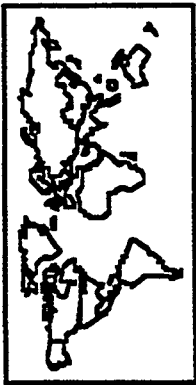
A LifePlan map has the following distinguishing characteristics: it is a visual, graphic display of the driving forces in the market, and the company's position along these critical dimensions of competition over time and relative to its competitors. Each of these elements is critical. The very purpose of a map is to provide a way to see the evolution and underlying trends in a market. Although good maps are based on data and analysis, pulling that analysis together in a visual format greatly enhances communication and innovation.

The LifePlan team is also very important, because mapping is most useful as a cross-functional communication and decision-making tool. The LifePlan team should be global and cross-functional, representing key business areas including discovery research, product/process development, medical, manufacturing, marketing, and finance. LifePlan responsibility should be a part of each team member's job.

LifePlan was adapted from a process and concepts developed by Dr. Steven Wheelwright and Dr. Kim Clark of Harvard Business School and several of their colleagues. Drs. Wheelwright and Clark have facilitated the use of the mapping process within the MDD companies and the Lilly manufacturing areas for several years. Most recently, it was used by the Leveraging Existing Products task force and four cross-functional mapping teams to determine how to Make the Most of Existing Products.

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LifePlan



Mapping our future...

What is the LifePlan Mapping Process?

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- **A strategic, product lifecycle planning tool**
- **A process for developing, presenting, and communicating an understanding of the critical issues / choices facing the business**
 - **Global**
 - **Cross-functional**
- **A framework for decision-making**

LifePlan

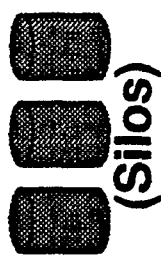


Improvement Over Conventional Planning

Mapping our future...

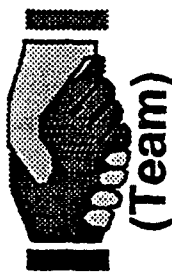
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Conventional Planning



Uni-Functional

(Silos)



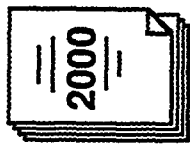
Cross-Functional

(Team)

LifePlan



Short Term



Long Term



One Country



Global



Product Driven



Customer Focused

LifePlan



A Way of Doing Business...

Mapping our future...

Why has Lilly chosen the LifePlan process as a way of doing business, now and for the future?

- **Formalizes the process of product lifecycle planning**
- **Optimizes the value of our portfolio**
- **Enhances the quality and diversity of both decision-making and implementation**
- **Strengthens commitment to the product**
- **Provides a roadmap for the future**

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LifePlan



Mapping our future...

LifePlan Team Membership

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Business Development

Global Medical

Discovery Research

Product / Process Development

Finance

Regulatory Affairs

Global Marketing

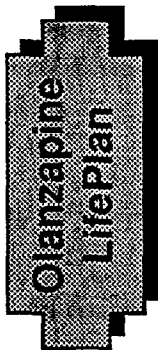
Global Market Research

**Pharmaceutical Projects
Management**

**Manufacturing Strategy /
Strategic Facilities Planning**

Health Economics

Corporate Affairs



LifePlan Team

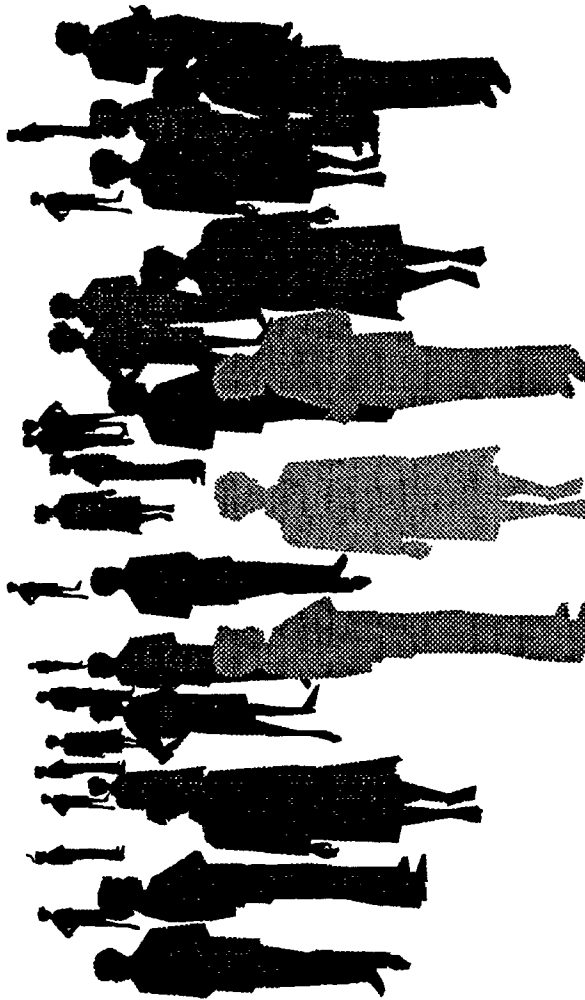


LifePlan Participants

- Catherine Mesner
- Gary Hadley
- Kelly Weston
- Russell Barton
- Paula Franz
- Pat Cowall-Hanover
- Kristine Kolling
- Beth Morris
- Winston Satterlee
- Deborah Good
- John Richards
- Jeffrey Kasher
- Yvonne Jones
- Philippe Bougard
- John Apathy
- Charles Beasley
- Laura Genduso
- Deborah Harrison
- James Ringer
- Thomas Van Abeele
- Nicholas Moore
- Roland Powell

Affiliate Visits / Planners

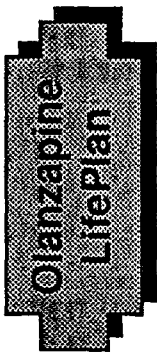
- Austria
- Canada
- France
- Germany
- Italy
- Hungary
- Netherlands
- Spain
- United States
- United Kingdom
- Belgium
- South Africa
- AMEGA
- Latin America
- Japan



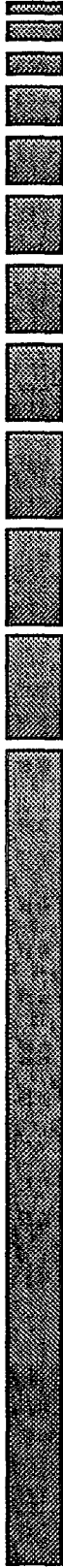
SECTION TWO

**Disease and Market
Overview**

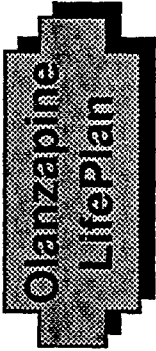
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Schizophrenia: Disease Overview



- Disease is characterized by two types of symptoms:
 - positive = delusions, hallucinations, thought disorders, bizarre behavior
 - negative = emotional blunting, flat affect, lack of motivation, social isolation
- A chronic and heterogeneous disease
- Not curable, but treatable with antipsychotics
- Significant comorbidity with other psychiatric disorders
- Generally onset between age 15 and 40
- One-year prevalence point of approximately 1%



Schizophrenia: Treatment Overview



• Over 90% of schizophrenic patients are diagnosed and treated by a psychiatrist

• Treatment objectives:

- Acute: Achieve control of presenting symptoms, often hospitalization is necessary

- Long-term: Prevent relapse and achieve social reintegration

• Current treatment:

- antipsychotics treat positive symptoms

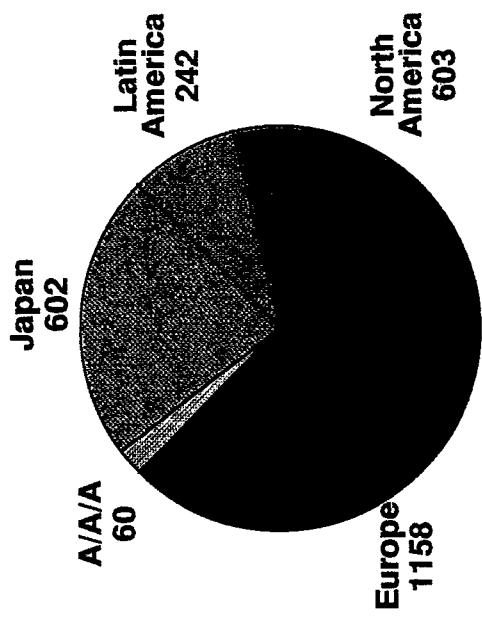
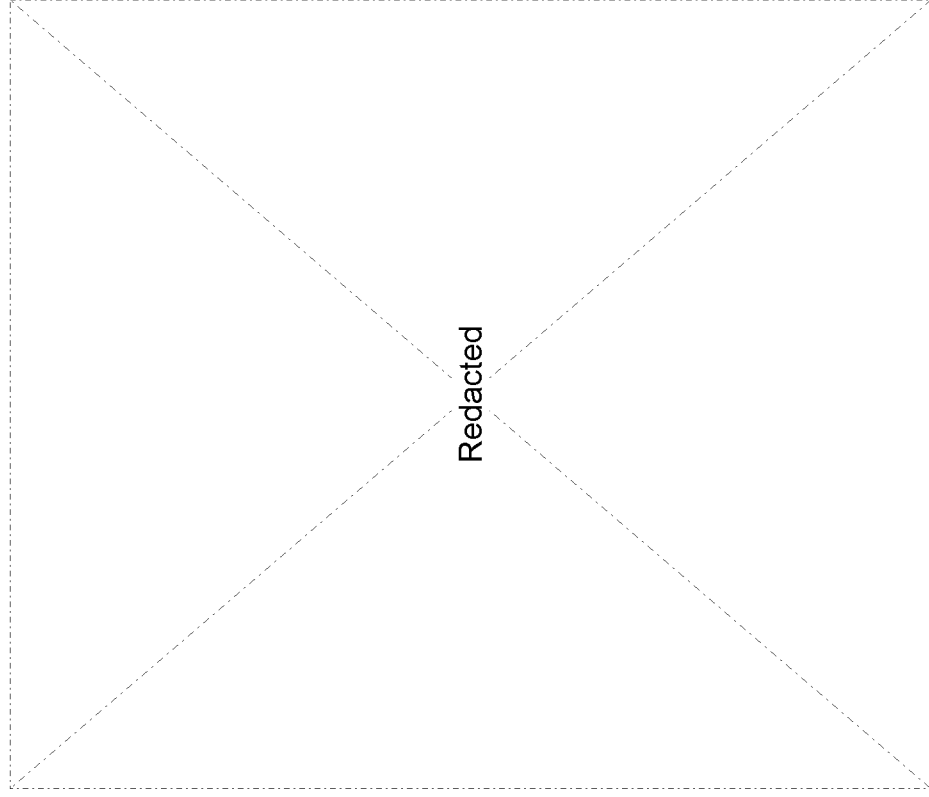
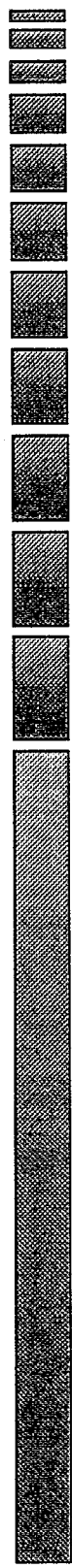
- a general lack of improvement in negative symptoms

- therapy associated with many side effects and compliance problems

• Treatment often intended to continue indefinitely

Olanzapine
LifePlan

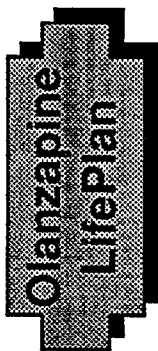
The Neuroleptic Market



2665 DOT

DOT (millions)

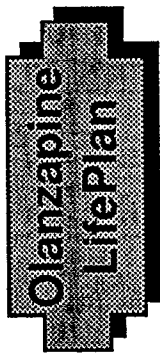




Formulations



- Oral solid is 58% of WW DOTs
- Depot, liquid, and granules for Japan are all essential for two reasons:
 1. Size of respective markets
 - depot 15% of WW DOTs
 - liquid 15% of WW DOTs
 - granules 31% of Japanese DOTs
 2. Strong link between usage with solid
- Short-acting IM 1% WW DOTs
 - the linkage between short-acting IM and solid is important
 - short-acting IM may have a big influence on perception of how “strong” our drug is



The Ideal Antipsychotic Drug



- **Improved treatment of negative symptoms**
- **Minimal serious side effects (i.e., EPS, T.D., akathisia, agranulocytosis)**
- **Efficacy in refractory patients**
- **Long-acting formulations for noncompliance**
- **Once-daily oral dosing**
- **Rapid relief (in days) of both positive/negative symptoms**

SECTION THREE

Driving Forces and MAPS

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LifePlan Driving Forces

- Increasing competition
- Changing customers and customer demands
- Nature of the disease and treatment
- Global market opportunity

Olanzapine LifePlan

Driving Forces

1. Increasing Competition

Over time, the global antipsychotic market is becoming increasingly competitive. Therefore, speed to market is critical. The market will become saturated with new products, raising the costs of entry into the market and the need to differentiate among products to gain market access. The optimal market opportunity is for a product with efficacy similar to clozapine and safety comparable to risperidone.

2. Changing Customers and Customer Demands

There is an increasing number of "customers" and a change in the balance of power among decision makers with regard to health care decisions. Powerful external forces are restricting prescribers' choices so that prescribers have less and less influence over time. There will also be increasing health care cost containment pressures over time. The "value" of health care products, services, or systems will increase focus on measures of outcomes, quality of life, and other economic parameters.

3. Nature of the Disease and Treatment

Diagnoses and treatment protocols for disorders classified as schizophrenia or psychoses are not clearly defined because the underlying causes of these illnesses are not fully understood. Cultural and country differences in the diagnosis and treatment of psychoses require an in-depth understanding of individual markets and customized country-specific approaches. Also, the complexity of patient management requires a variety of formulations. Patient non-compliance is a significant factor that affects treatment outcome.

4. Global Market

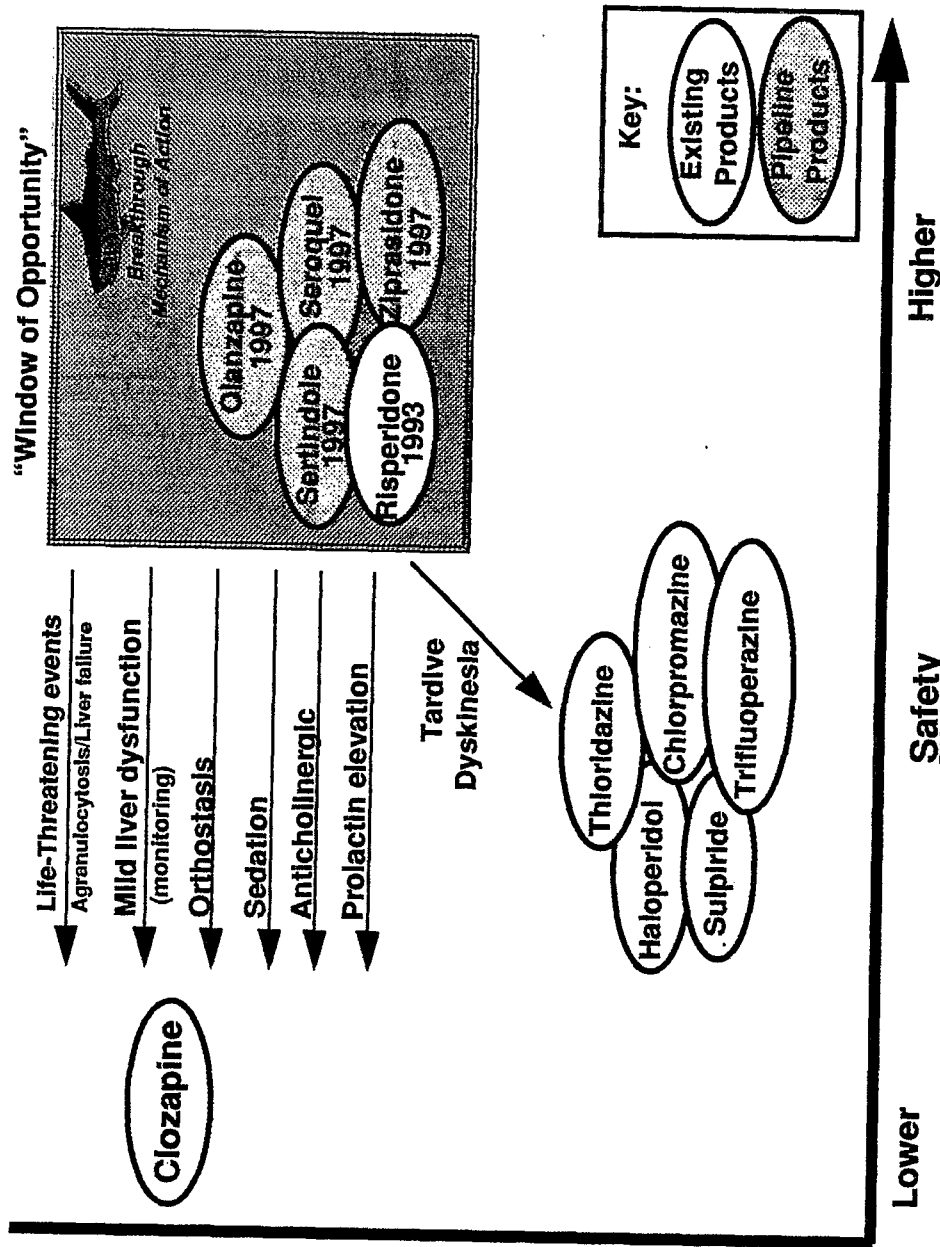
Traditional, industrialized markets will experience minimal growth in population and health care expenditures per capita. Cost containment pressures will continue in these markets. Emerging markets will demonstrate an increasing need and ability to pay for modern health care, providing important new business opportunities. During the next ten years, the top pharmaceutical companies will be those that add participation in emerging markets to their participation in established markets.

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Antipsychotic Market Opportunity is for a Drug with
"Clozapine-like" Efficacy and Improved Safety

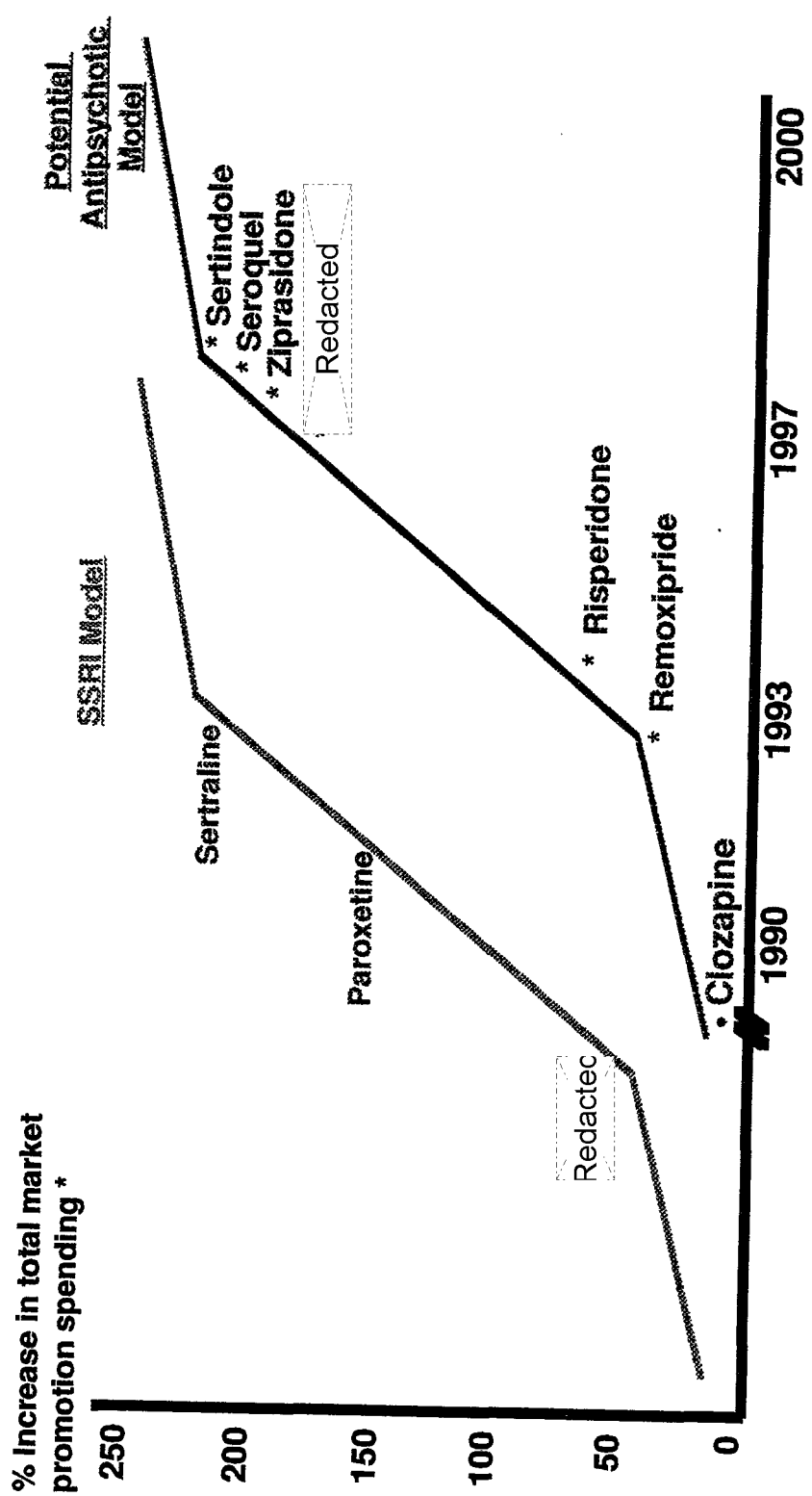
Improved
Efficacy and
QOL; Reduced
Schizophrenia
Symptoms



Olanzapine Life Plan 2/22/94
Driving Force #1



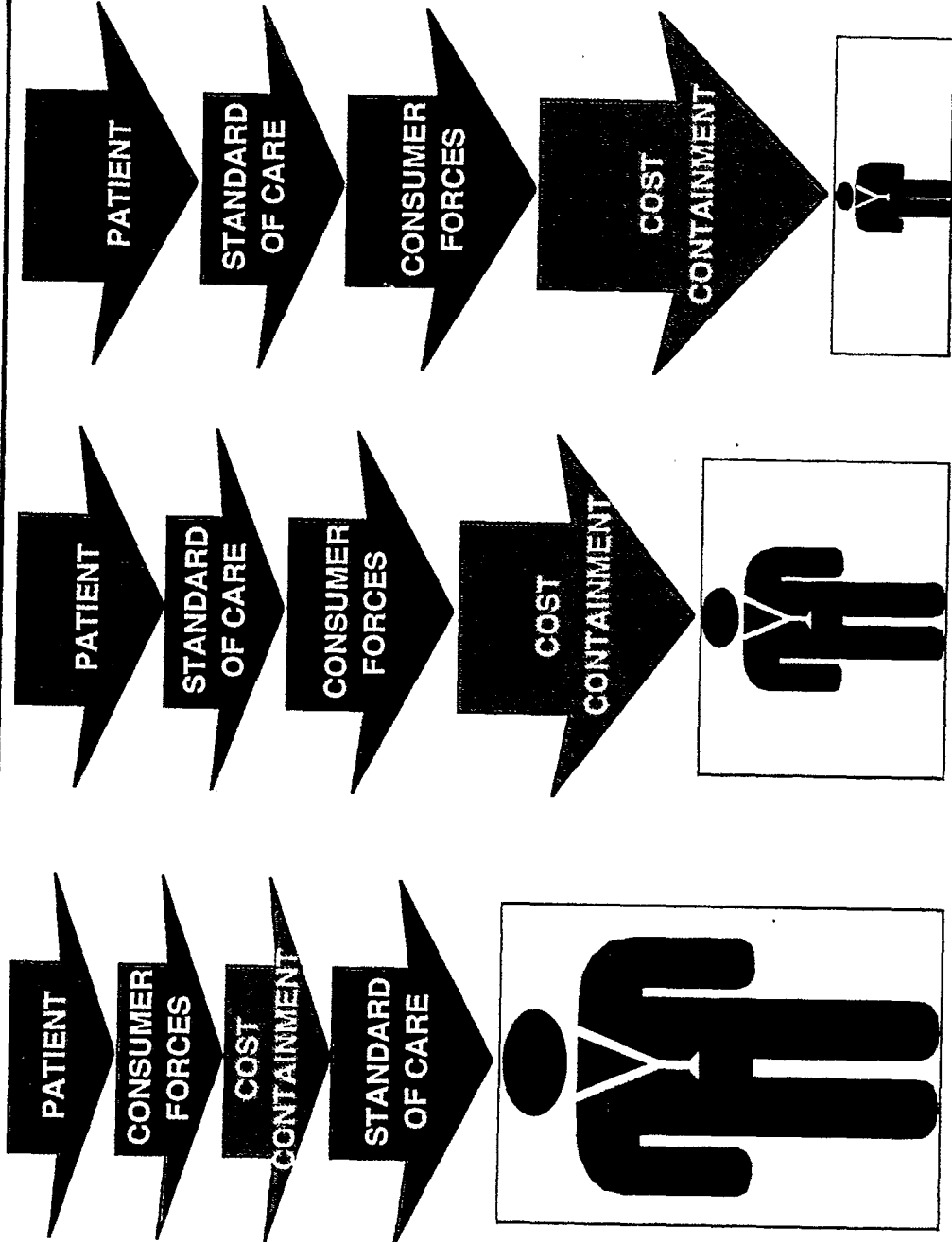
The Competitive Antipsychotic Market Leads to Higher Costs of Entry and Increased Importance of Differentiation



* Based on model of SSRI Impact on spending in the UK antidepressant market



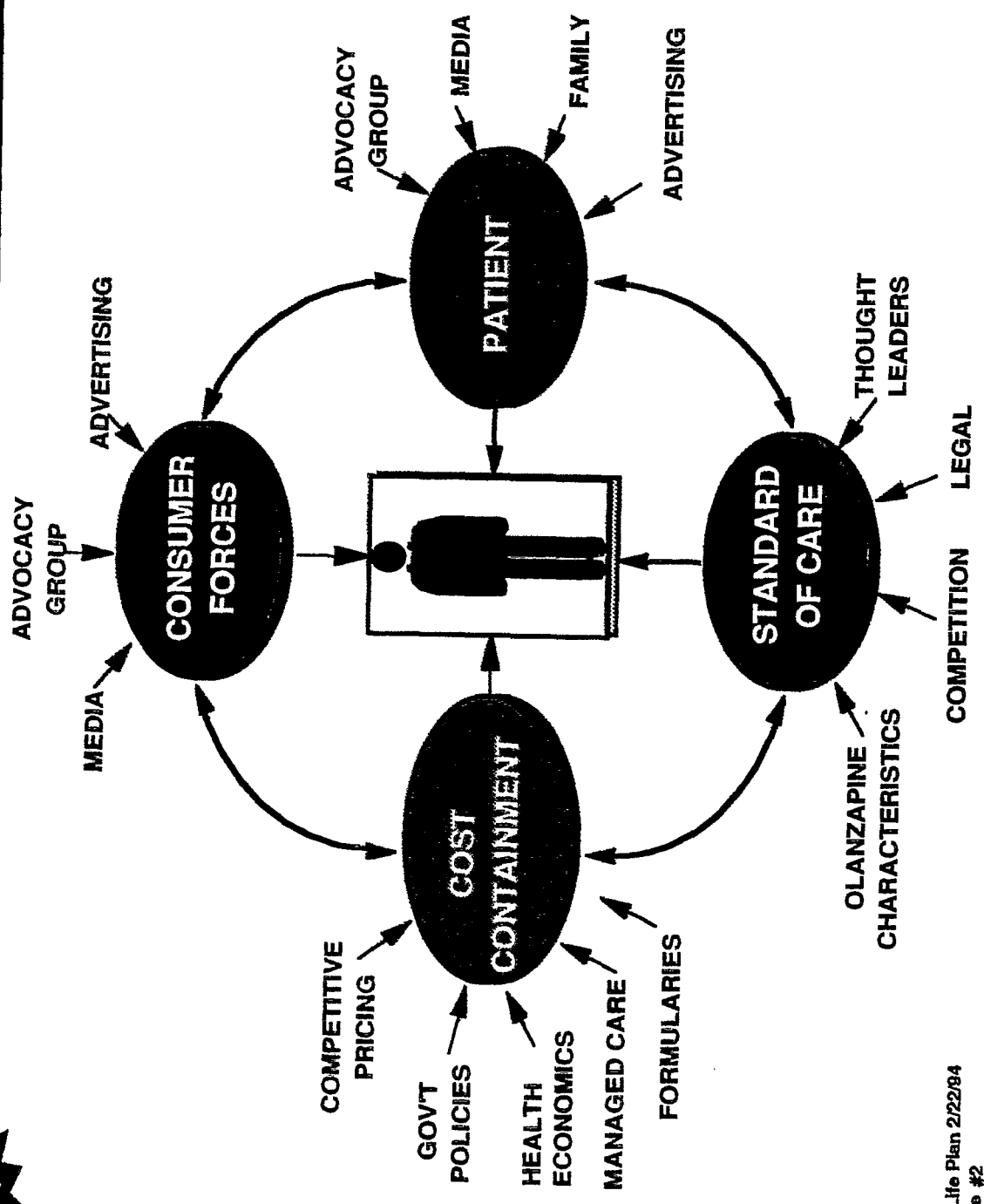
Increasing Pressures are Limiting the Prescriber's Freedom of Choice Among Drug Therapies



Olanzapine Life Plan 2/22/04 Driving Force #2 1990 1995 2000



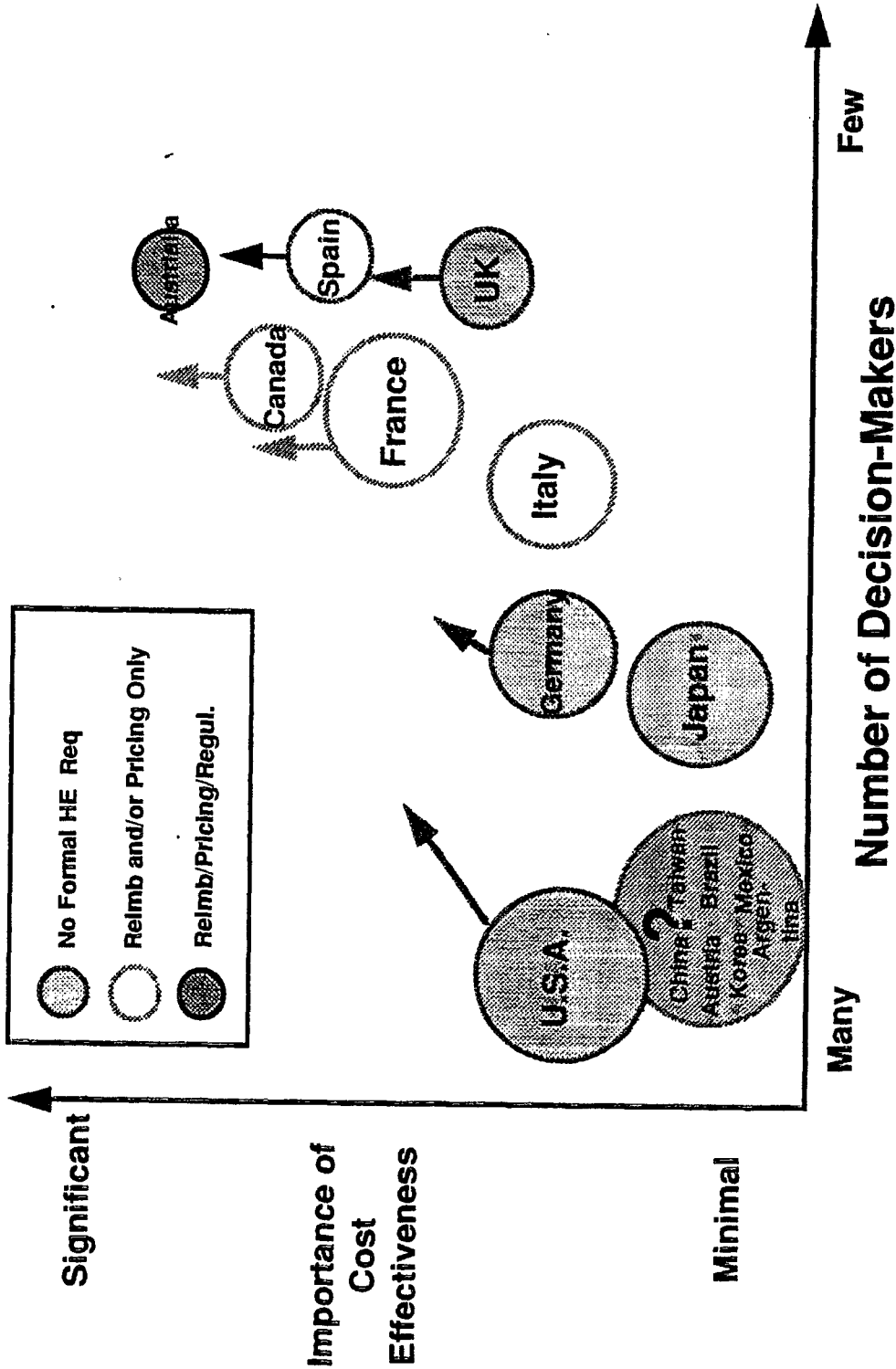
Pressures on the Prescriber



Olanzapine Life Plan 2/22/94
Driving Force #2

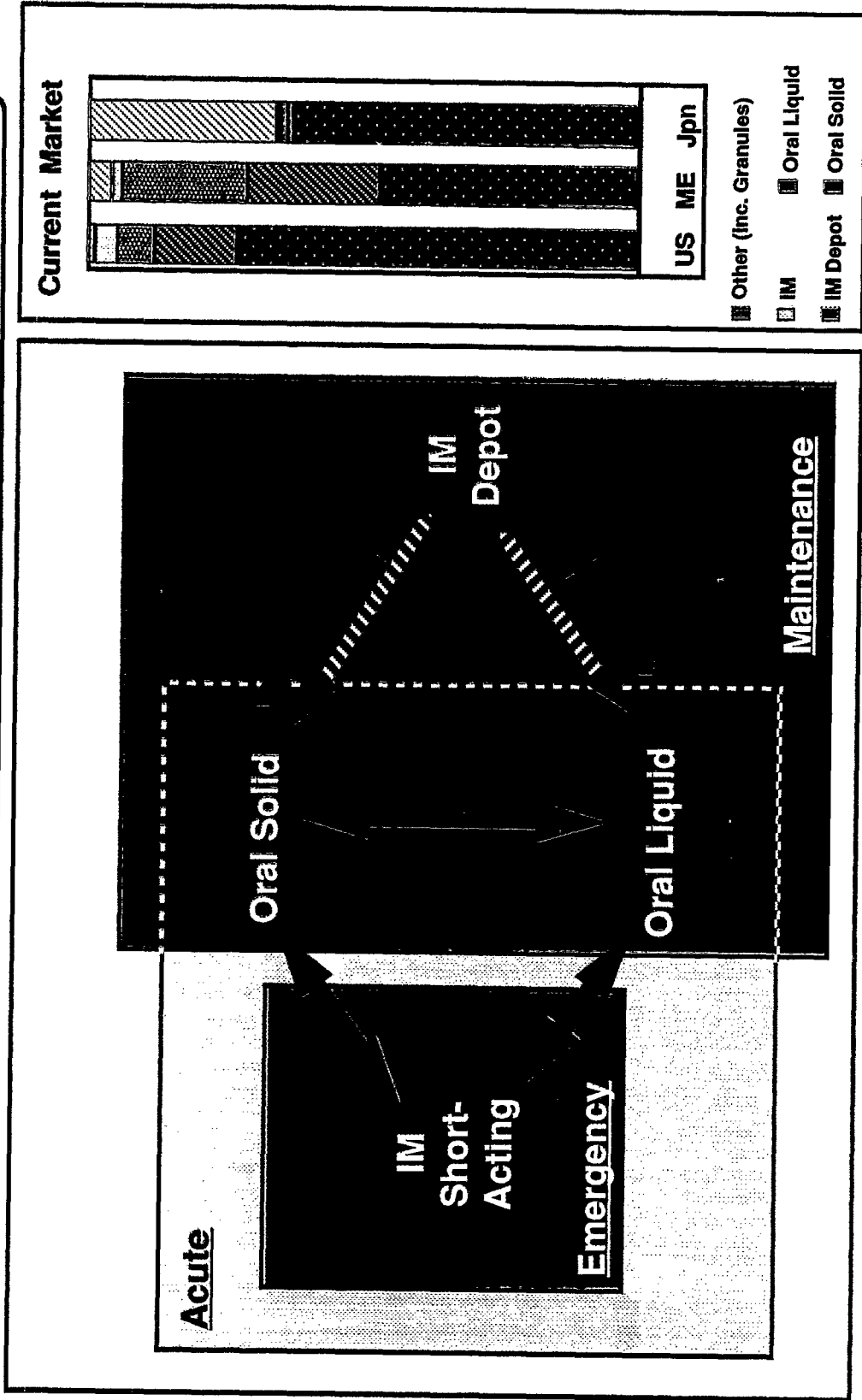


Cost Containment Pressures Lead to the Need for Health Economic Data and Reduce the Number of Decision Makers





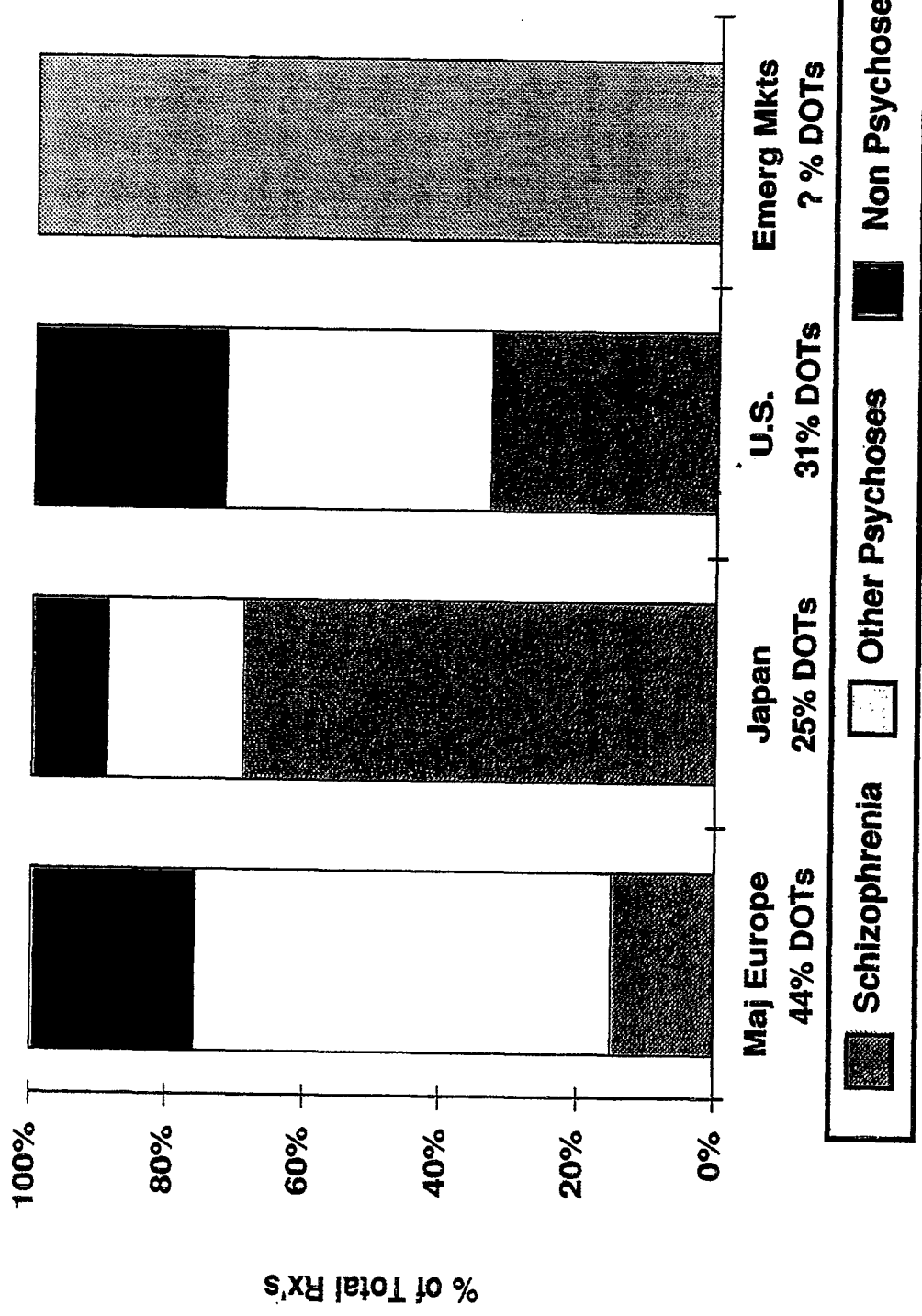
**Complex Patient Management Requires
a Broad Range of Formulations**



Olanzapine Life Plan 2/22/94
Driving Force #3



Cultural and Country Differences Impact the Diagnosis and Treatment of Psychoses

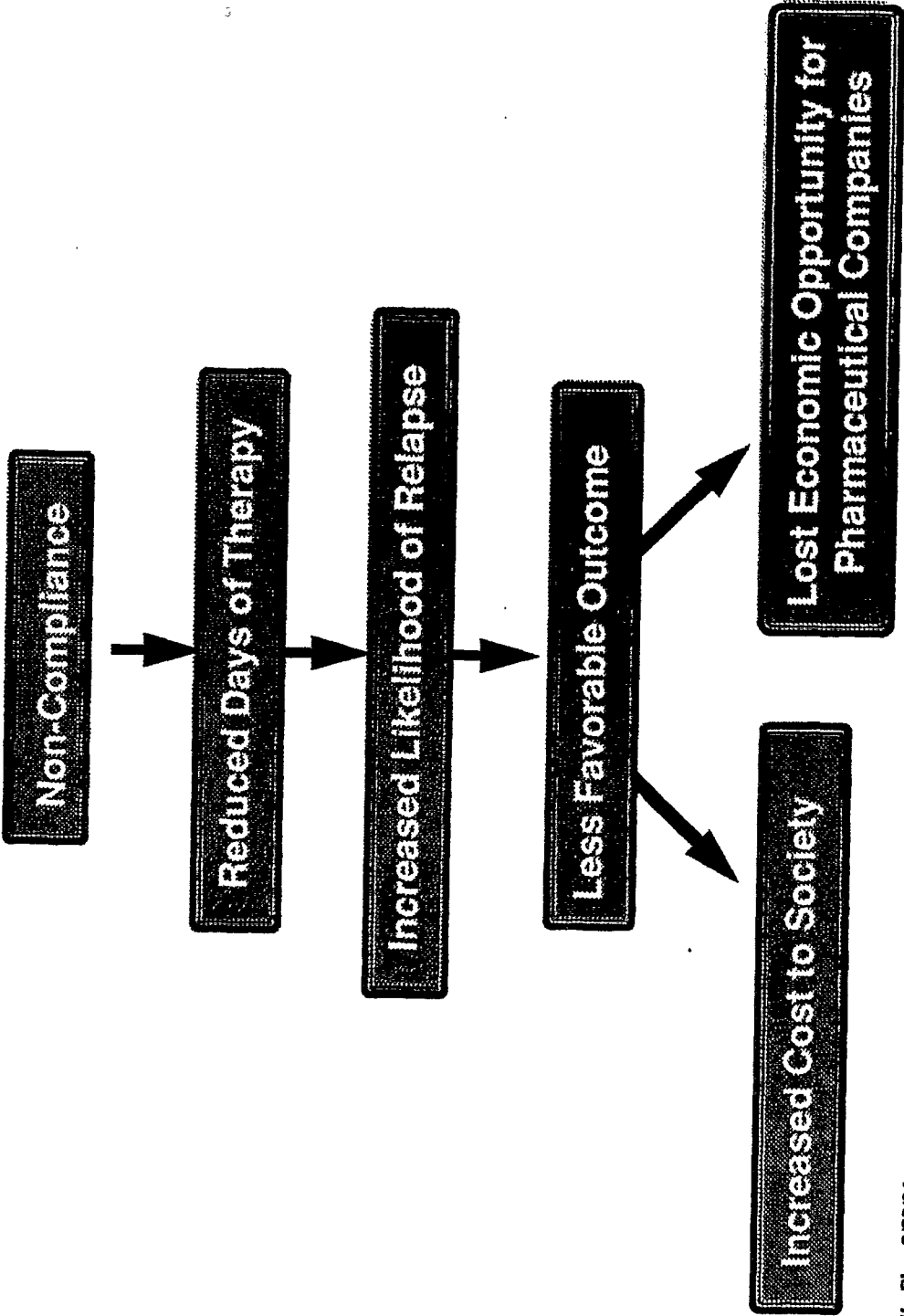


Olanzapine Life Plan 2/22/94
Driving Force #3

Source: Antipsychotic Desk Research 3/24/92

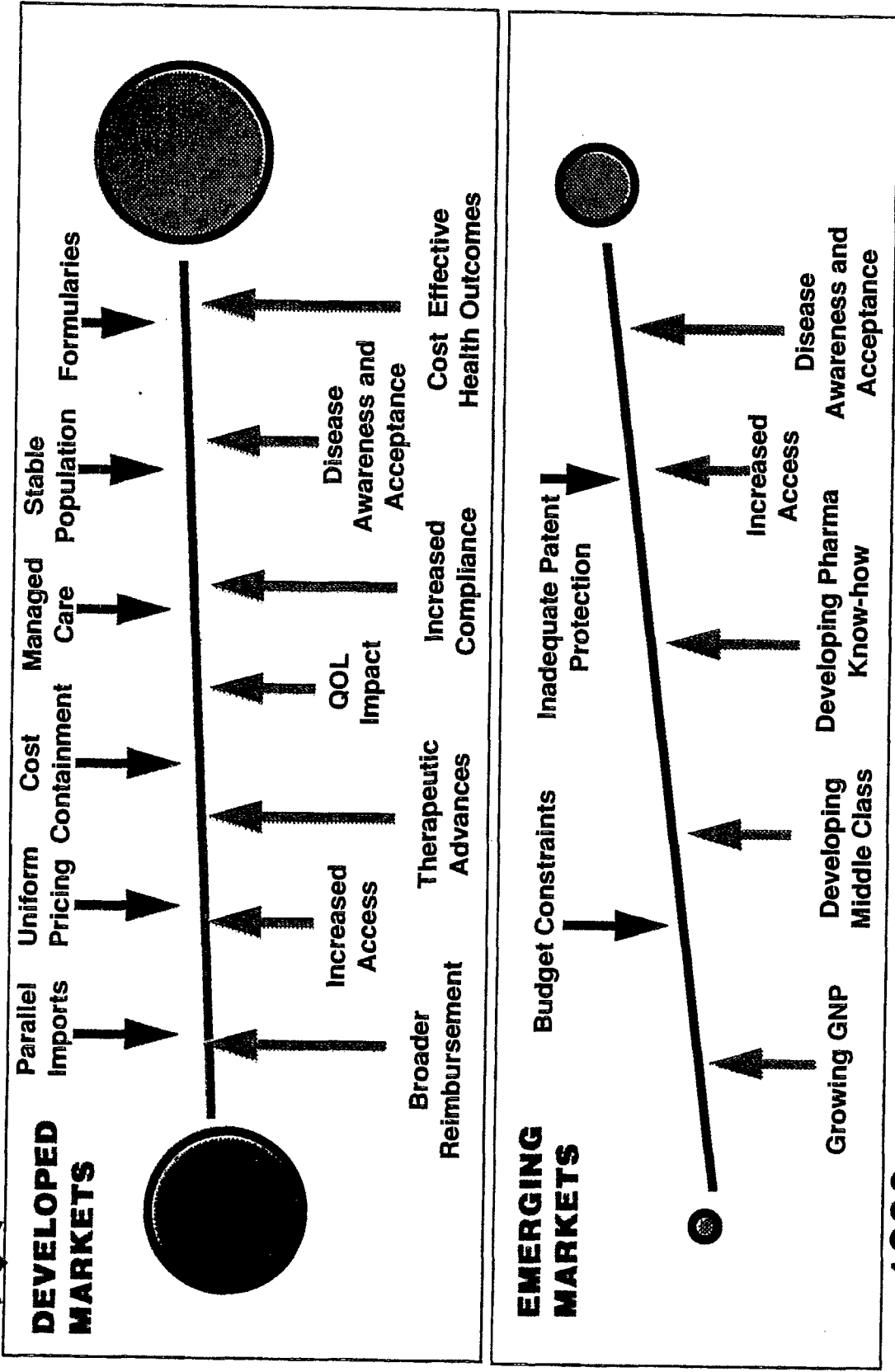


Patient Non-Compliance Affects Treatment Outcomes





Factors Affecting Global Psychoses Market Opportunities

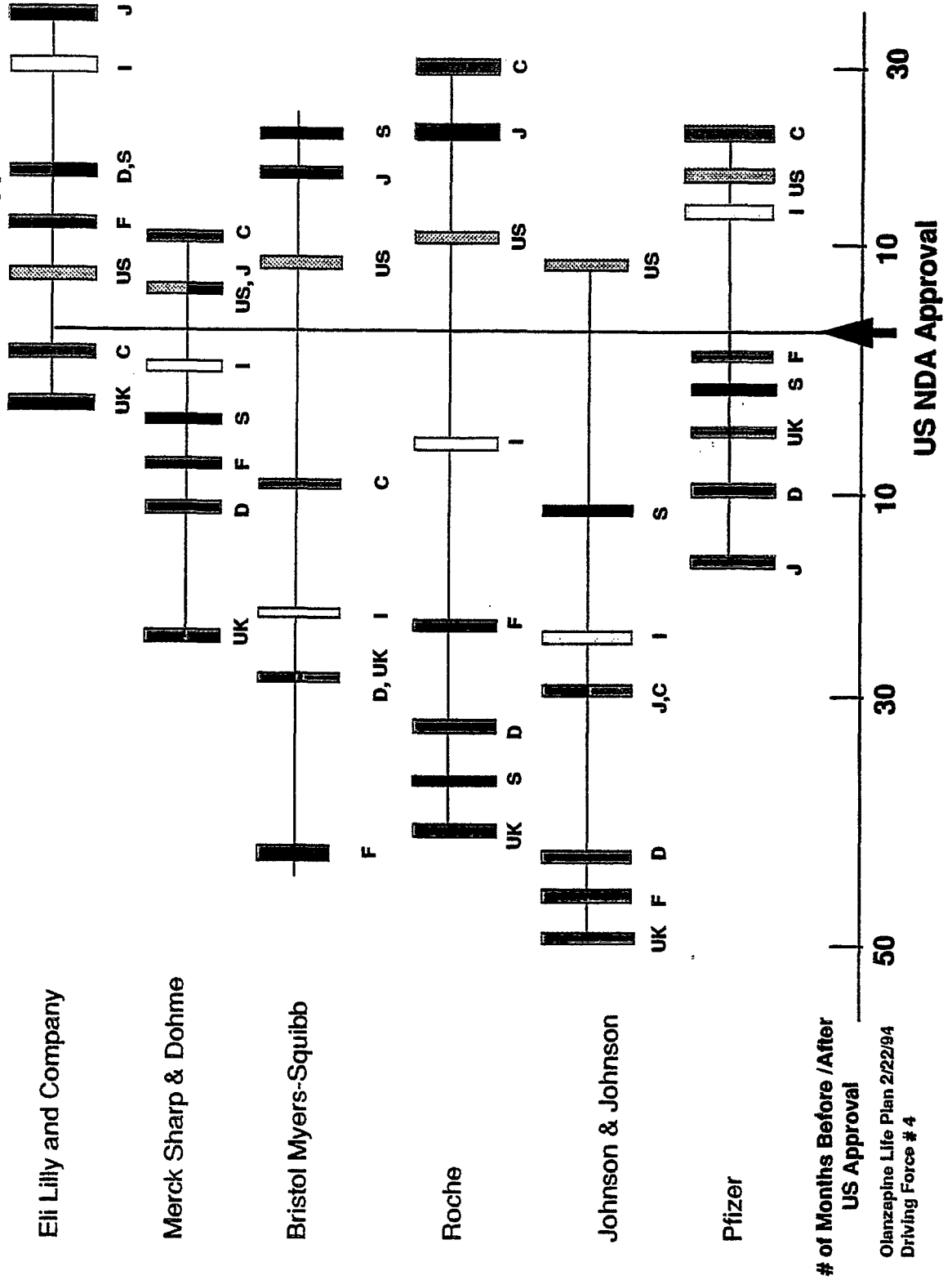


Olanzapine Life Plan 2/22/04
Driving Force #4

Implementation of a Global Registration Strategy will Speed Olanzapine to Market and Increase Economic Returns

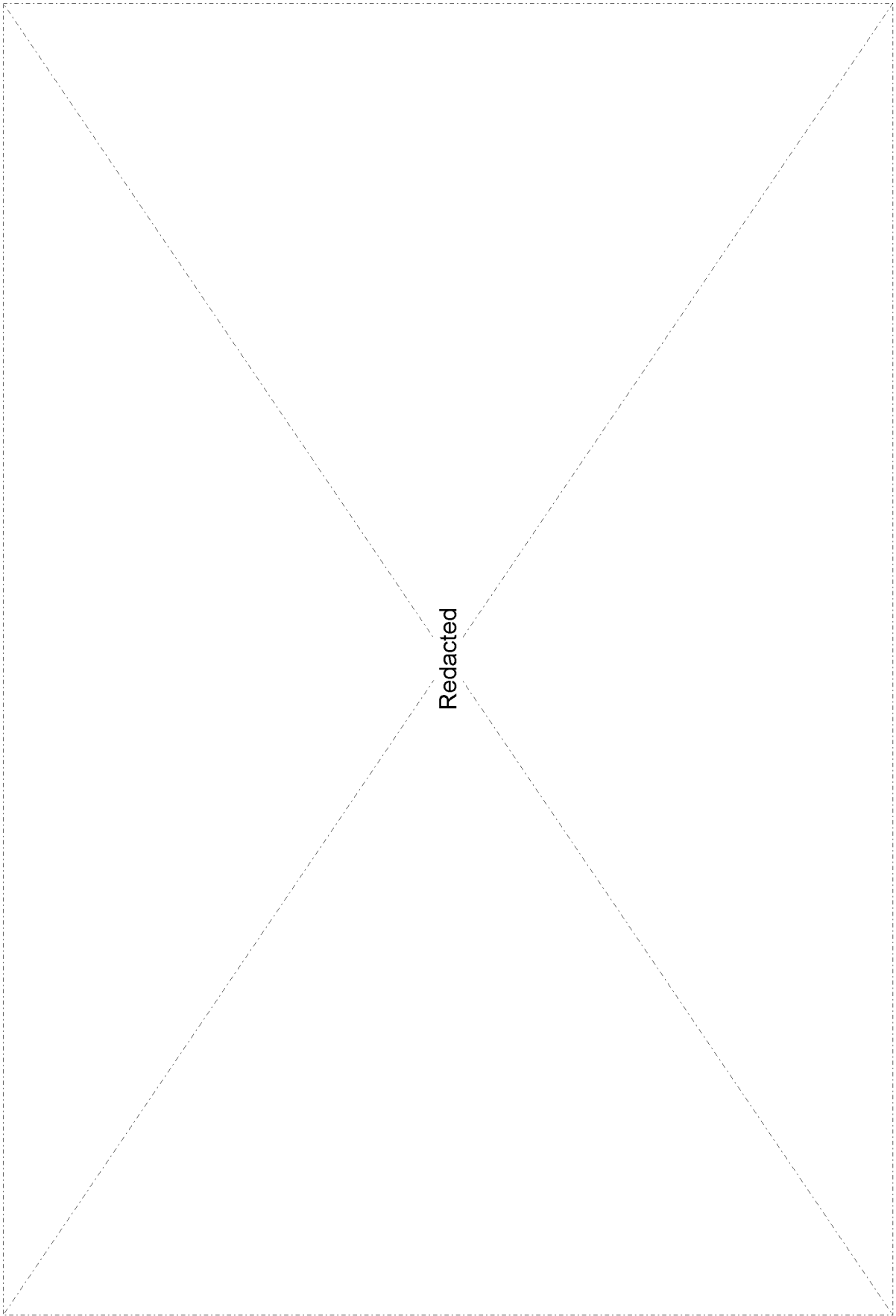


Historical Timing of Product Launches Relative to US NDA Approval



of Months Before / After US Approval
 Olanzapine Life Plan 2/22/94
 Driving Force # 4

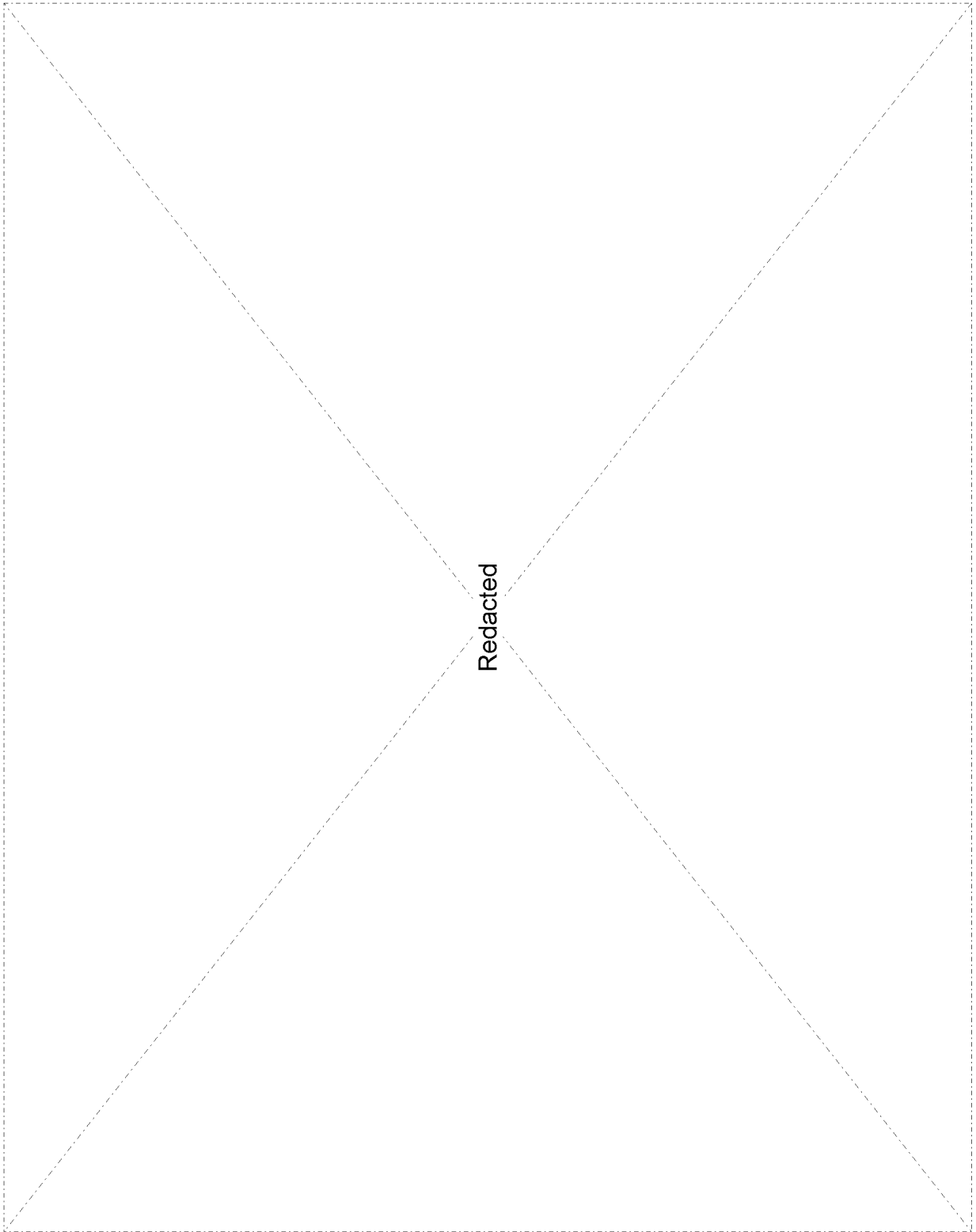
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Olanzapine Life Plan 2/22/04
Driving Force # 4

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BMS DATA % Indicates Dollar Growth 1990-92

Olanzapine Life Plan 2/22/94
Driving Force # 4

SECTION FOUR

Business Strategy

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LifePlan Strategic Intent

- Be next**
- Be better**
- Be global**

OLZ LifePlan/Europe
GRH:bw 2/22/94

Olanzapine LifePlan

Summary of Strategic Initiatives

1. Speed to Global Markets:

Due to the increasing competitiveness of the market and the growing importance of worldwide market opportunities, we will secure regulatory approval in all key markets as quickly as possible.

2. Develop a Customer-Focused Product Development Plan:

The complexity of the disease and the varied approaches to patient management requires a variety of product formulations. Formulations and packaging tailored to meet customer needs will enhance compliance and improve outcome. We will provide world markets with the most appropriate product presentations of olanzapine.

3. Redefine Standard of Care in Disease Management and Establish Olanzapine as the Standard of Pharmaceutical Care

In order to be successful, we must demonstrate that olanzapine, relative to our competitors, delivers economically and clinically optimal outcomes. We will work to redefine what the standard of care outcome should be and how olanzapine plus other measures will deliver this desired outcome.

4. Aim for Rapid and Broad Market Penetration:

We will conduct aggressive pre and post-launch marketing initiatives designed to influence share determiners and meet the needs of our target customers: patients, caregivers, providers, and payors.

5. Participate in Emerging Markets:

Given that the percentage of population suffering from schizophrenia or other psychoses is constant across geographical and cultural boundaries, countries such as India, China, and others become important markets for olanzapine. Population and health care expenditures will remain relatively stable in many traditional markets, while emerging markets will demonstrate an increasing need and ability to pay for modern health care. Therefore, we will develop and implement plans that will enable us to gain access to and participate in these emerging markets.

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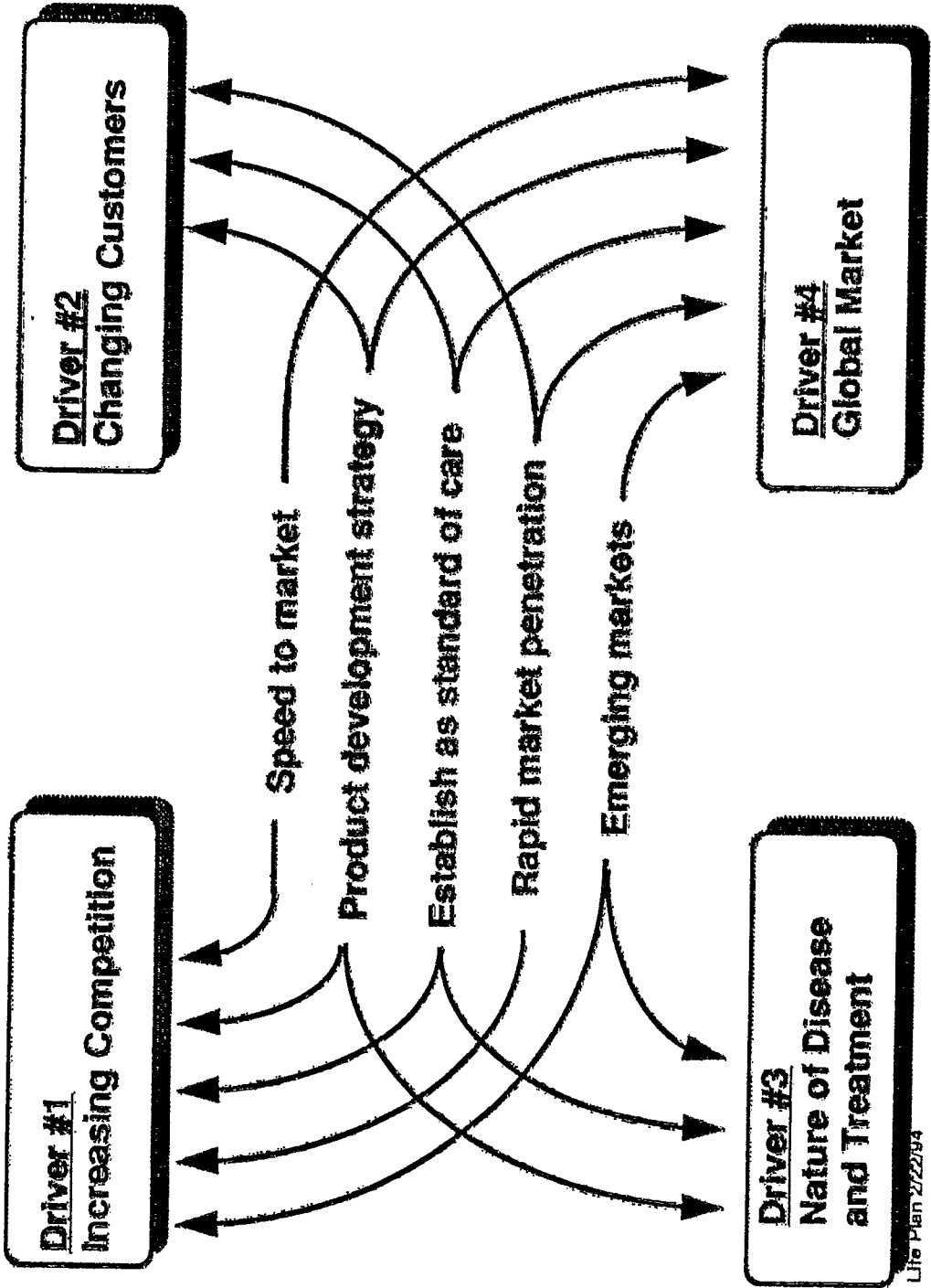
OLANZAPINE

LifePlan Strategic Initiatives

- **Speed to global markets**
- **Customer focused product development plan**
- **Redefine standard of care and position olanzapine as the standard of pharmaceutical care**
- **Aim for rapid and broad market penetrations**
- **Participate in emerging markets**



Linkages Between Olanzapine Driving Forces and Strategic Initiatives



Olanzapine Life Plan 2/22/94
Driving Force

Strategy 1: Speed to Global Markets

1.1 Develop a registration strategy to ensure submission by October 1995 in North America, Europe, Israel, South Africa, and Australia Submit in Japan by October, 1996.

- Identify current resources and headcount for registration in all affiliates and compare with the level of resources needed to address critical registration issues
- Explore options (consulting, hiring, redeployment) to gain registration expertise and resources at corporate and affiliate levels
- Build business case for pursuing option to gain global registration expertise

1.2 Coordinate medical, regulatory, and marketing efforts and resources (corporate and affiliate) to expedite submission in Free Sale Certificate (FSC) countries within 60 days of first approval in the United Kingdom.

- Establish a working group with regulatory and core team members

1.3 Cultivate key relationships with global regulatory authorities in order to facilitate speed of registration review and approval

- Monitor competitor interaction/relationships with regulatory authorities
- Determine critical factors to speed regulatory approval
- Identify key decision-makers of registration process in targeted markets and strengthen relationships

1.4 Continue to improve understanding of the evolving regulatory environment to ensure speed to market for future line extensions

- Monitor competitors' registration strategies and tactics
- Monitor regulatory guidelines

1.5 Develop an integrated plan to launch olanzapine oral formulations within 60 days of regulatory and pricing approval in each country

- Form an affiliate launch team by regulatory submission date to expedite launch
- Coordinate efforts among medical, manufacturing, marketing and sales, and other areas critical to a successful launch
- Integrate pricing and marketing strategies into launch plans

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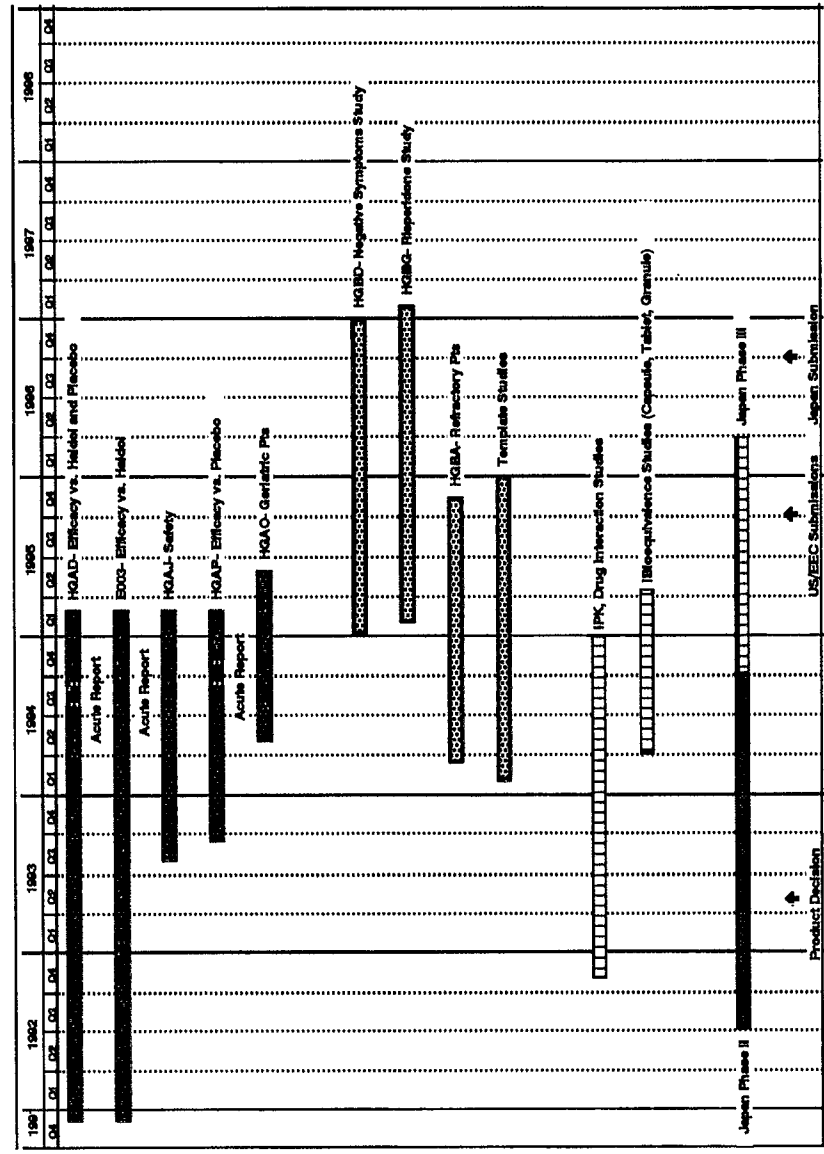
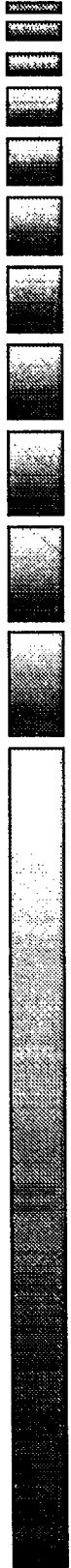
Speed to Global Markets



- **Develop a registration strategy to ensure regulatory submissions by October 1995 in North America and EEC, and October 1996 in Japan**
- **Submit in Free Sale Certificate (FSC) countries within 60 days of approval in the U.K.**
- **Cultivate key relationships with global regulatory authorities to facilitate speed of review**
- **Develop an integrated plan to launch**



Development Timeline



Strategy 2: Customer-Focused Product Development Plan

2.1 Conduct market research to understand formulation / packaging needs of customers

- Identify critical questions regarding formulation needs, wants and concerns
- Review previous market research and fill gaps
- Incorporate data from psychosis segmenter
- Seek input from affiliates
- Collaborate with advocacy groups/advisors/providers
- Determine sampling and packaging needs of global markets

2.2 Develop formulation priorities based on customer input

- Develop a detailed overall timeline for development and launch of each formulation
- Develop business case to support formulation strategy
- Incorporate into CM&C, medical and marketing plans

2.3 Continue rapid development of multiple strengths of tablets for launch

- Develop detailed timeline requirements
- Incorporate timelines into CM&C, medical and marketing plans
- Make decision on bottle size and bulk sourcing
- Make decision on tablet / imprinting
- Revisit tablet strengths required, prior to the start of process validation

2.4 Continue rapid development of granules and reconstitutable granules for launch

- Beiersdorf to complete work on reconstitutable granule/Japan granule

2.5 Develop short-acting IM

- Develop general project timeline and requirements
- Complete market research and develop business case
- Develop toxicology, ADME and medical timeline and requirements
- Position as a line extension.
- Initiate and complete feasibility studies
- Obtain GPAC approval
- Identify development and DPM resources to support effort (impacts depot, short-acting IM -- anything that proceeds beyond feasibility stage)

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2.6 Develop depot formulation

- Develop toxicology, ADME and medical timeline and requirements
- Incorporate into CM&C, medical and marketing plans
- Complete feasibility studies
- Obtain GPAC approval to proceed with development
- Decide on formulation technology; develop 3rd-party contract and timeline
- Establish critical development checkpoints
- Position as a line extension

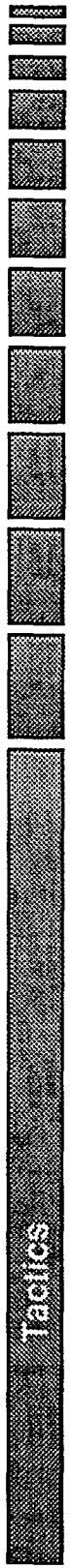
2.7 Pursue other innovative delivery forms as line extensions

- Conduct feasibility studies and market research on the following:
 - Zydis fast dissolving tablet technology. Acquire an exclusive contract with RP Scherer if possible. Obtain GPAC approval to proceed
 - Obtain GPAC approval to proceed with development of transdermal delivery system
 - Investigate ready to use micro-emulsion
 - Investigate implantable dosage formulation
- Develop business case and incorporate into overall development plans as appropriate

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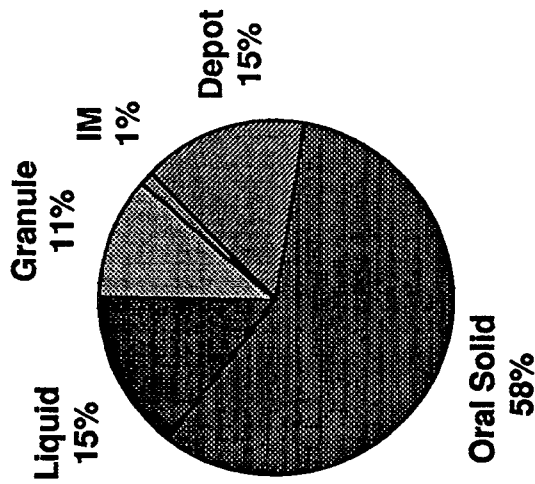
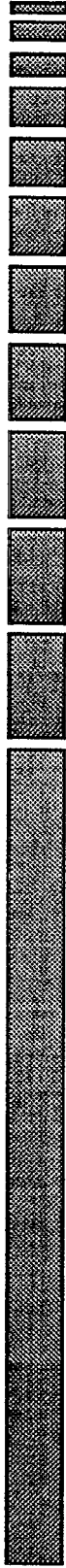
Develop a Customer-focused Product Development Plan



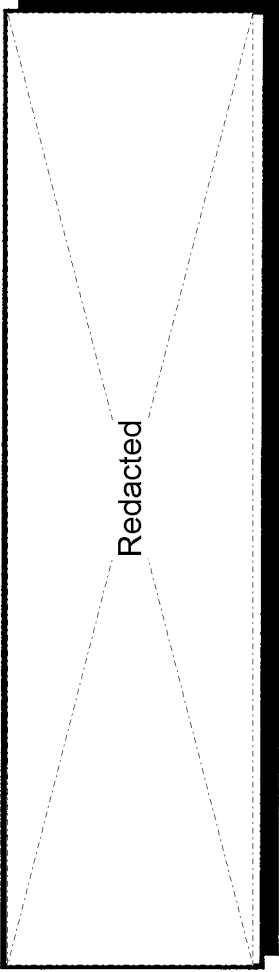
- Conduct market research to understand formulation and packaging needs of customers
- Establish formulation priorities based on customer input



Develop a Customer-focused Product Development Plan

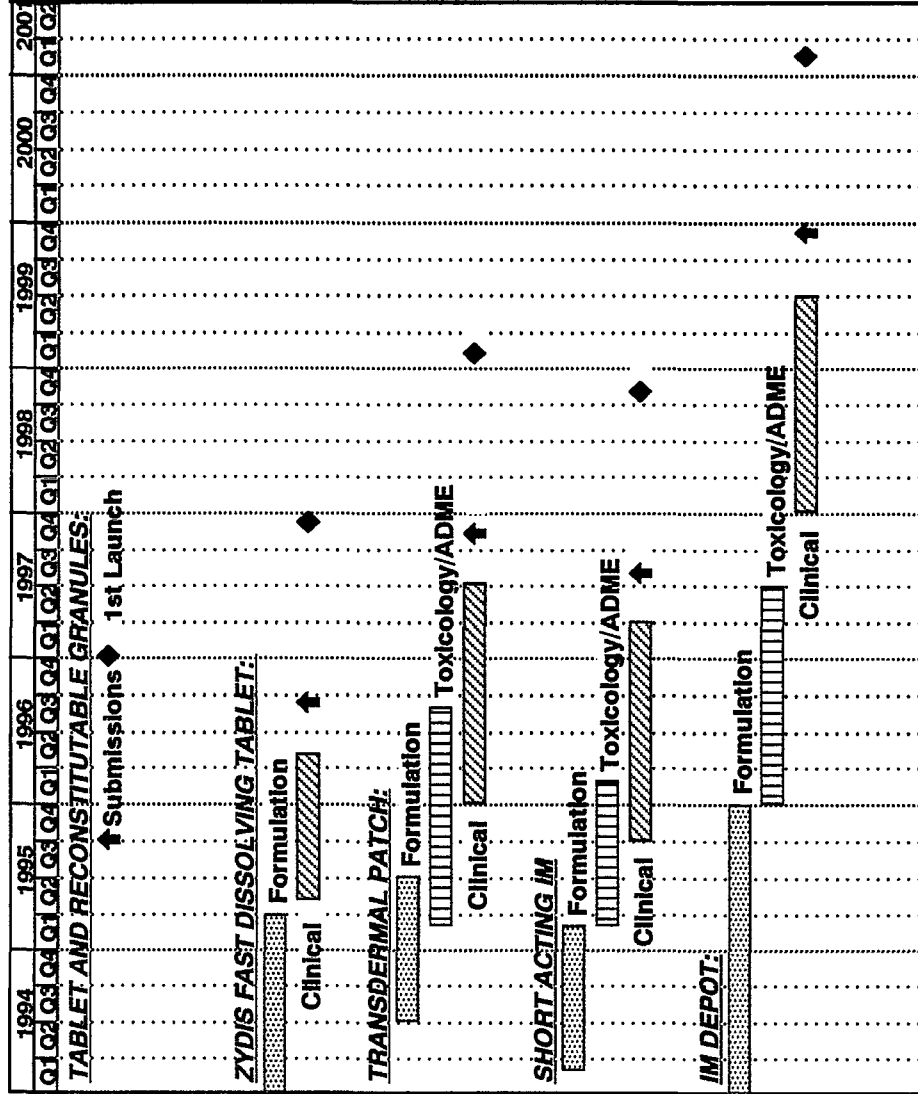


- Offensive
 - ▲ # DOTS (IM, depot)
 - ↔ # DOTS (tablet → Zydys; tablet → depot)
 - Deliver optimal outcomes
- Defensive
 - Lack of dose form ▼ # DOTS
 - competition



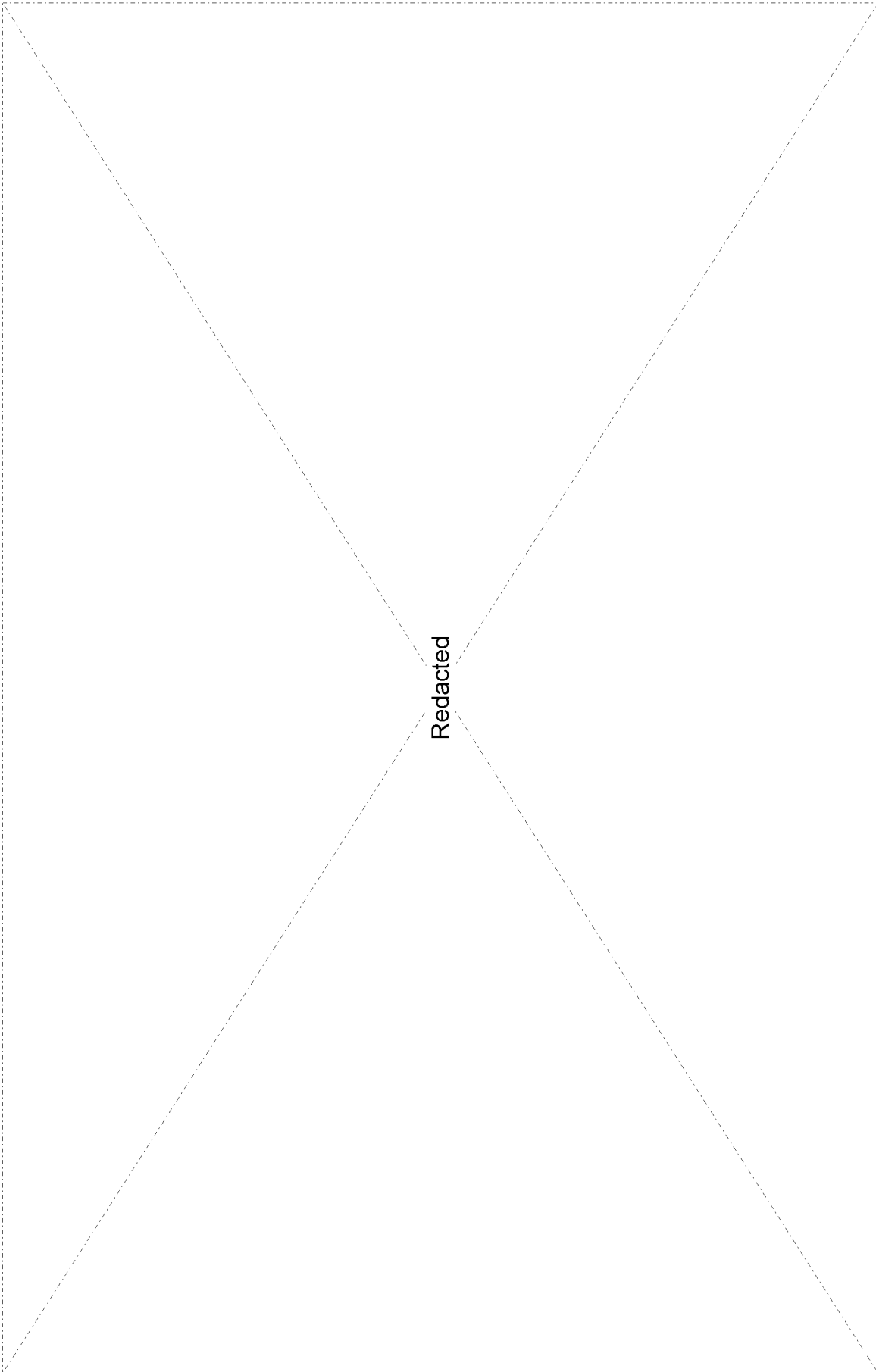


Clinical Plan - All Formulations



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Year

Strategy 3: Establish Olanzapine as THE Standard of Care

3.1 Through global and country-specific clinical trials, demonstrate olanzapine's combined safety and efficacy profile and differentiate it from the competition. Market opportunity is for a "safer clozapine." However, the major competitor at launch is likely to be risperidone.

- Design clinical trials to demonstrate the following:
 - Efficacy in positive and negative symptoms
 - Low / absent tardive dyskinesia and EPS
 - Low / absent elevation of prolactin
 - No significant monitoring required
 - Superior safety relative to clozapine and typical antipsychotics
- Demonstrate similar efficacy to clozapine in treatment-resistant patients
- Demonstrate similar safety to risperidone
- Clinical trials planned or underway include:
 - Pivotal efficacy (HGAD, E003,, HGAP) and safety (HGAJ)
 - clozapine treatment-resistant paradigm, risperidone comparator, negative symptom study, geriatric study
- Conduct country specific template studies and Plan D trials to address country-specific issues, broaden product use and sustain market share
- Develop a post-marketing safety and adverse event surveillance system

3.2 Obtain broad package labeling to expand use and address global differences in diagnosis

- Understand geographic and cultural differences in disease management
- Determine desired labeling in major markets
- Conduct appropriate country-specific trials to maximize opportunities in key markets

3.3 Develop health economics (HE) and quality of life (QOL) data

- Form a global health economics strategy team
- Consult with HE experts in designing assessments and outcome measures
- Incorporate HE and QOL measurements in clinical trials to gain "core data package"
- Conduct additional country-specific HE, QOL, and outcome studies or analysis as needed to supplement core data package
- Use HE and QOL data to obtain optimal pricing/reimbursement, formulary access; and to demonstrate optimal outcomes.

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3.4 Position olanzapine as part of an overall patient (disease) management system that focuses on achieving optimal outcomes.

- Determine the non-pharmacologic needs of varied customers, decision-makers necessary to achieve optimal outcomes
 - diagnostics
 - related products, devices, services, and delivery systems
 - education and information tools and materials
 - vocational and support skill training
 - community support programs
- Develop programs or services to enhance compliance
- Provide formulations and packaging to address the needs identified above
- Assess the need and opportunities for vertical and/or horizontal integration
- Develop treatment algorithms and use guidelines

3.5 Develop an effective corporate communications plan

- Identify key audiences that influence disease treatment and product success (internal, consumer, media, general public, legal, advocacy groups, policy-makers, health care providers/payors)
- Develop key messages using data from market, product and health economics research to effectively communicate with each audience
- Develop effective means and materials to communicate to each audience and assign responsibility for implementation
- Coordinate with broader efforts to position Lilly as CNS leader
- Provide core package of communication tools for affiliates to use and tailor to specific country communications needs
- Build capacity to respond to medical information requests

3.6 Develop a plan to "redefine" optimal standard of care

- Define elements of dissatisfaction with current treatments
- Conduct gap analysis
- Develop programs and services aimed at correcting treatment deficiencies.
- Position olanzapine (along with programs and services) versus the competition, as meeting more of our customers unmet needs.
- Use outcomes data to achieve a "most valued pharmaceutical partner" status with our customers

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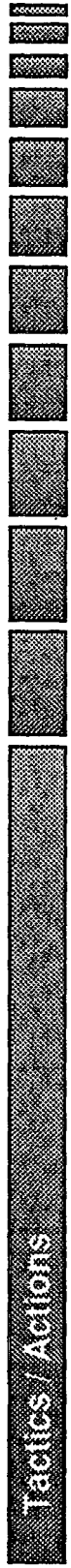
**Redefine the Standard of Care Via Disease Management
and Establish Olanzapine as the Standard of
Pharmaceutical Care**



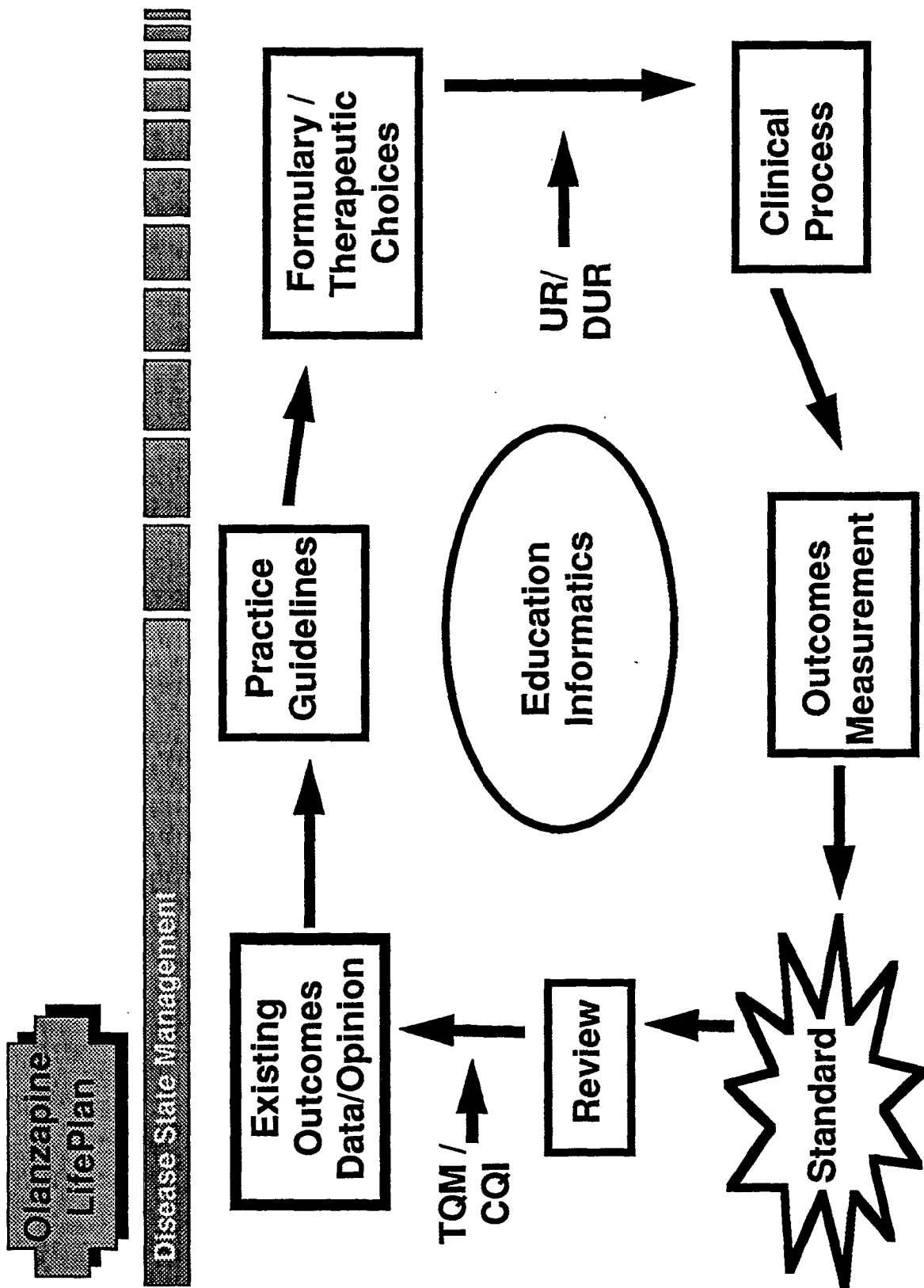
- **Through global and local clinical trials, demonstrate olanzapine's safety and efficacy profile and differentiate it from the competition**
- **Obtain broad package labeling to expand use and address global differences in diagnosis**
- **Develop health economics (HE) and quality-of-life (QOL) data**



**Redefine the Standard of Care Via Disease Management
and Establish Olanzapine as the Standard of
Pharmaceutical Care**



- **Position olanzapine as part of an overall patient (disease-state) management system that focuses on achieving optimal outcomes**
- **Develop a plan to “redefine” optimal standard of care**
 - **position olanzapine (along with programs and services) vs the competition, as meeting more of our customers’ unmet needs**
 - **use outcomes data to achieve a “most valued health care partner” status with our customers**



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Strategy 4: Market Penetration Strategy

4.1 Develop a country-specific marketing strategy based on country and cultural differences in the diagnosis and treatment of schizophrenia and related psychoses.

- Clearly identify the key customers in each market and frame critical questions concerning their needs, wants and concerns in the treatment of schizophrenia and related psychosis
- Conduct market research at both corporate and affiliate level
- Utilize information available from the psychosis segmenter
- Develop customer and country-specific marketing strategies
 - Target primary customers, i.e. patients and caregivers, providers, and payors as identified by market research.
 - Target secondary customers, i.e. government, managed care, advocacy groups, etc.

4.2 Develop a branding strategy

- Select a single global trademark
- Contract with a professional branding company (i.e. Lewis and Gace)
- Brand olanzapine with an outcome that is in concert with plans to brand Lilly as a CNS leader
- Develop a "crystallized product promise" in association with our disease state management strategy

4.3 Undertake aggressive pre-launch marketing activities

- Monitor competitors to determine "noise level" in this competitive market
- Position Olanzapine as a safe Clozapine-like atypical which provides optimal clinical and economic outcomes using:
 - Publications plan (country / market specific)
 - Advocacy group collaborations for each country
 - Identification of opinion leaders in each country
 - Utilization of input from US and international advisory boards
 - Participation in key meetings (symposia, posters, presentations, abstracts)
 - Demonstration of positive health economics and QOL data at launch
- Hold periodic olanzapine planners meetings.
- Fill affiliate product manager positions 18 months prior to launch
- Develop treatment algorithms and use guidelines
- Affiliates must budget for and obtain adequate resources to implement pre-marketing strategies and programs (LifePlan)

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4.4 Implement post-launch marketing strategy to gain broad market access

- Utilize a portfolio of products / services approach where appropriate
- Build "aligned promotion" strategies with major customers
- Design and implement educational and service programs
- Adopt competitive pricing policy to maximize market share
- Evaluate strategic alliances and co-marketing opportunities
- Evaluate opportunities for new indications (see 4.6)
- Introduce line extensions in a planned manner
- Develop publication and meeting / symposia plans for the product life-cycle
- Evaluate capitation type patient management programs

4.5 Identify channels of distribution

- Conduct market research on patient service segments and corresponding distribution
- Develop plans to facilitate customer access to product
- Understand and integrate distribution plan with corporate strategy

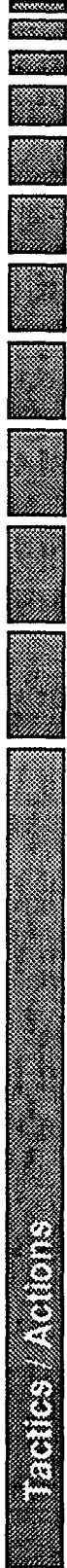
4.6 Evaluate new indications and off-label indications

- Refractory bipolar disorder
- Psychotic depression
- Personality disorder with psychotic features
- Non-drug induced organic mental disorders
- Mania, bipolar disorder
- Drug-induced mental disorders
- Attention deficit disorder
- Dementia with psychosis
- Children/Adolescent use

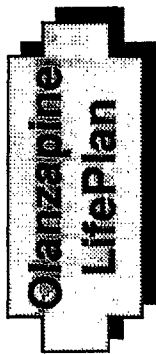
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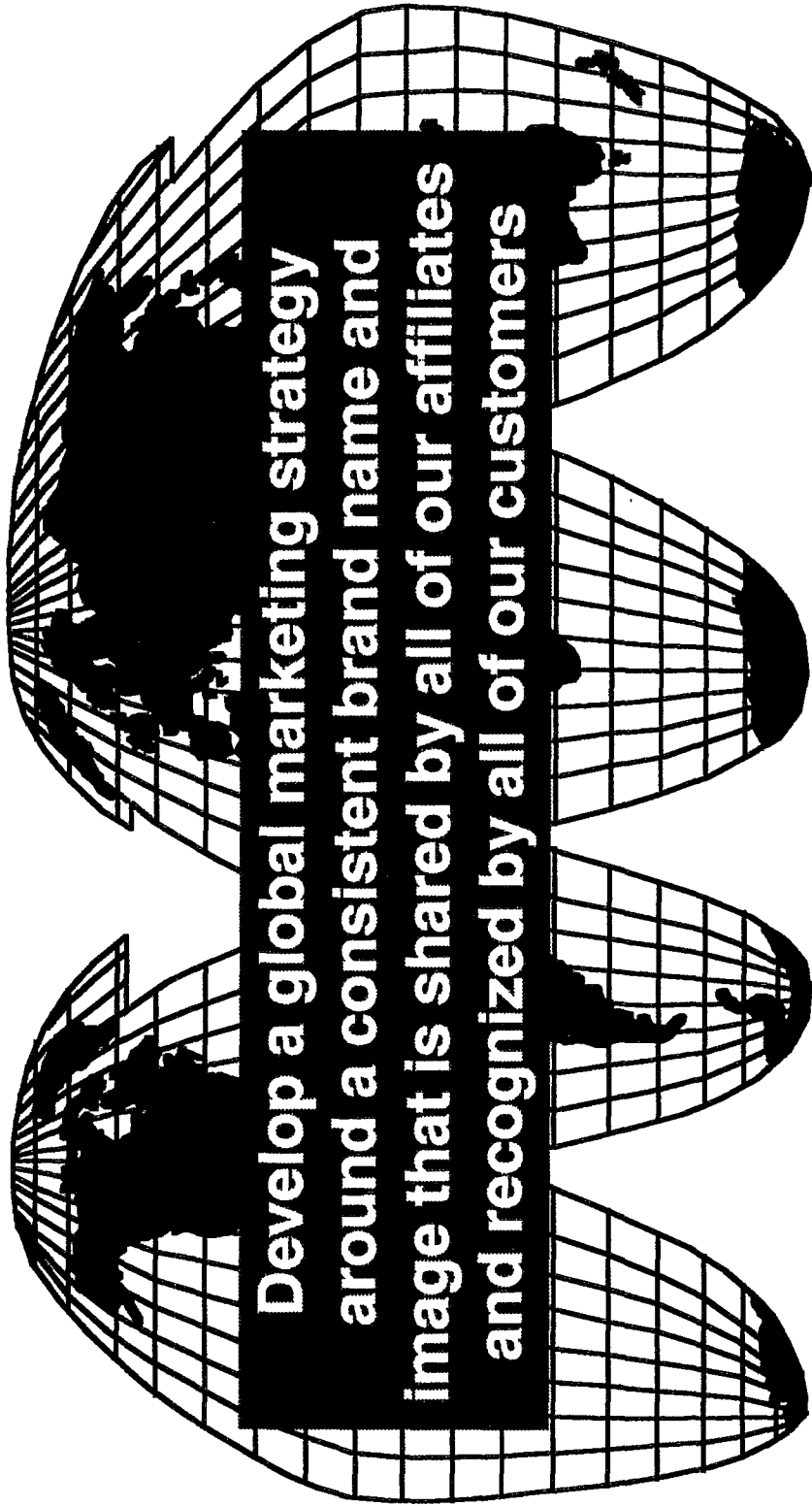
Aim for Rapid and Broad Market Penetration



- **Undertake aggressive pre-launch marketing activities**
 - **position olanzapine as a safe clozapine-like atypical agent which provides optimal clinical and economic outcomes**
 - **planners meetings**
 - **obtain affiliate resources to implement pre-marketing strategies and programs**



Aim for Rapid and Broad Market Penetration



**Develop a global marketing strategy
around a consistent brand name and
image that is shared by all of our affiliates
and recognized by all of our customers**



Aim for Rapid and Broad Market Penetration

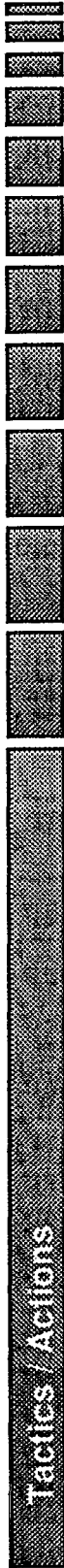


The benefits of strong, consistent Rx product 'branding':

- Increases 'recall' and 'top-of-mind' awareness with physicians and consumers
- Optimizes promotional spending and cost efficiencies
- Makes products more resistant to competitive challenges through the product life cycle



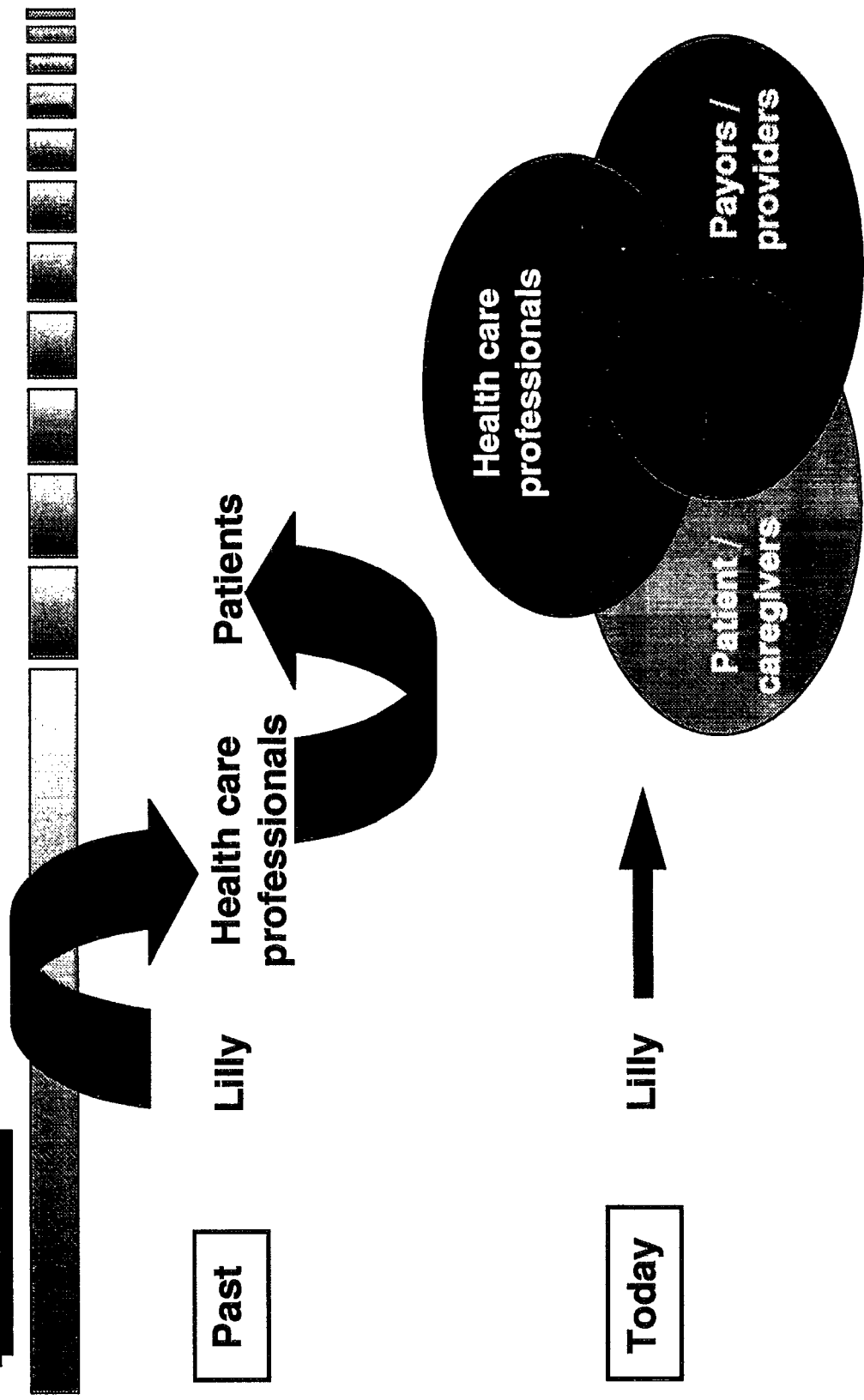
Aim for Rapid and Broad Market Penetration



- **Implement post-launch marketing strategy to gain broad market access**
 - do what it takes (i.e., strategic alliances, bundling products / services, risk sharing)
 - competitive pricing to maximize market share
 - evaluate opportunities for new indications
 - introduce line extensions in planned manner
 - develop publication and symposia plans
- **Develop an effective corporate communications plan**

Olanzapine Lifeplan

Aim for Rapid and Broad Market Penetration



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Strategy 5 : Participate in Emerging Markets

5.1 Prioritize markets based on economic and strategic value

- Evaluate opportunities in emerging markets
- Identify potential for strategic fit with other Lilly existing and future products
- In conjunction with regional management, identify and prioritize local market opportunities and allocate resources accordingly

5.2 Assess and build corporate presence in priority markets

- Determine what resources Lilly currently devotes to each market
 - Source of support and staffing levels
 - Strategic alliances, etc.
- Determine options for developing presence in high priority markets
 - Identify key contacts
 - Build near-term presence by starting a dialogue with these contacts
- Develop / Leverage Strategic Alliances
 - Joint ventures
 - Local consultants
 - Partnerships with established companies

5.3 Develop marketing plans to successfully launch olanzapine in the prioritized countries

- Identify and build relationships with key opinion leaders
- Pre-launch activities
- Conduct market research
- Identify sales force requirements

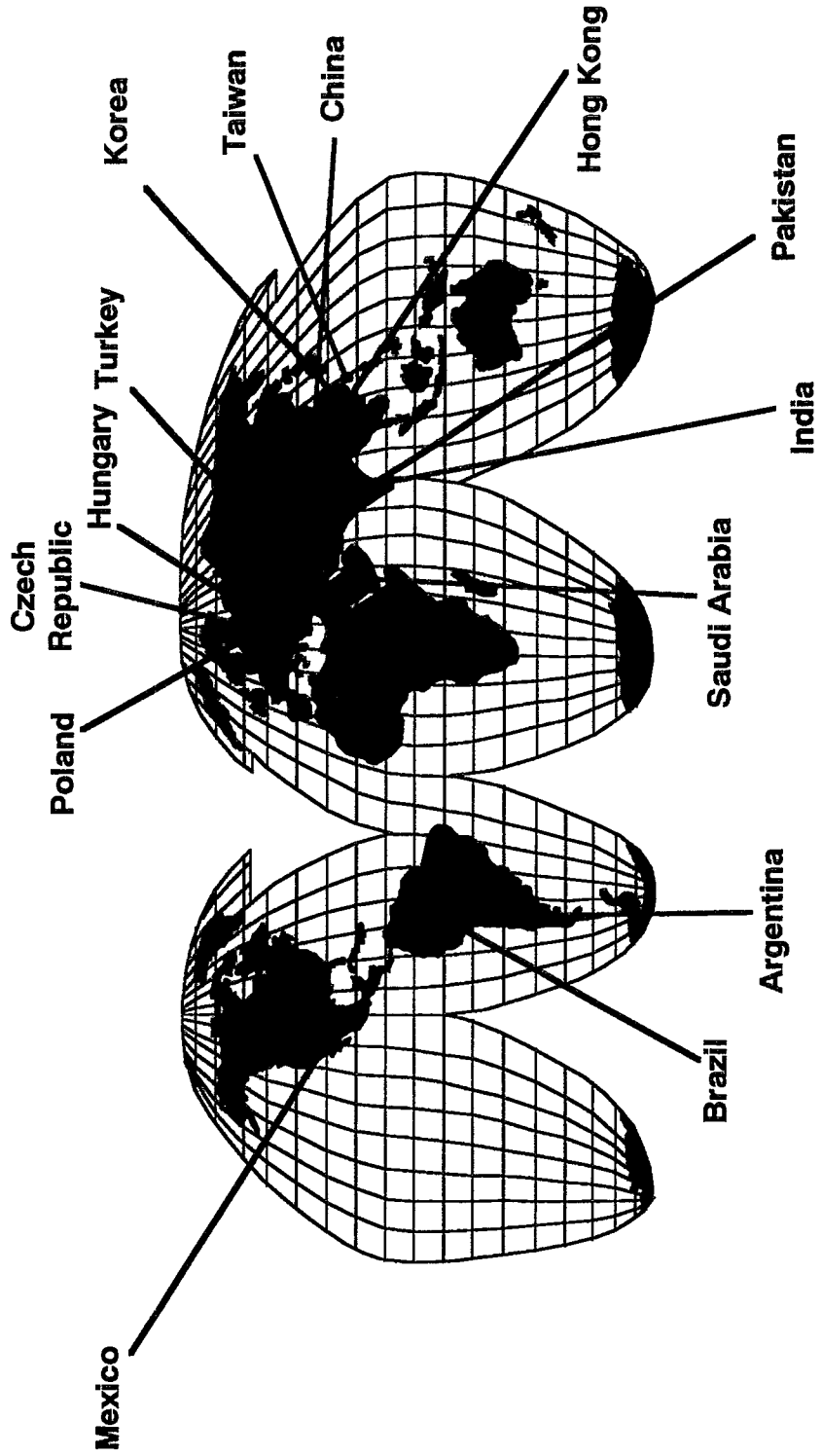
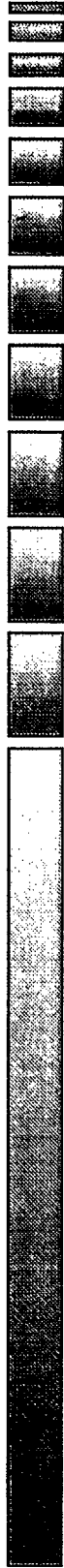
5.4 Enter into identified emerging markets with coordinated medical, marketing, global registration, and pricing strategies

- Determine regulatory and registration requirements
- Determine resources necessary to register olanzapine with quality speed
- Understand country specific manufacturing restrictions
- Determine and conduct required pre-registration clinical trials
- Develop pricing strategies for Free Sale Certificate countries

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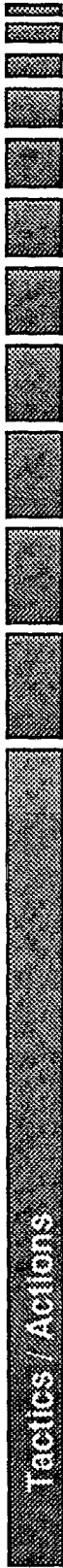
Emerging Markets



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Participate in Emerging Markets



- **Prioritize markets based on economic and strategic value**
- **Assess and build corporate presence in priority markets**
- **Enter into markets with coordinated medical, marketing, registration and pricing strategies**

SECTION FIVE

Aggregate Action Plan

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OLANZAPINE LIFEPLAN AGGREGATE ACTION PLAN

Action	Responsibility	1994				1995				1996				1997				1998			
		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Strategy #1: Speed to Market:		Strategy #1: Speed to Market																			
Registration Strategy	Core Team J. Kasher, P. Tran	██████████																			
Coordinate free sale submissions	Core Team/Regulatory J. Kasher, P. Tran	██████████																			
Relationships with global regulatory	Core Team/Reg/Affiliates J. Kasher, P. Tran	██████████																			
Understand regulatory environment	Core Team/Reg/Affiliates J. Kasher, P. Tran	██████████																			
Integrated launch plan	Core Team/Launch Team J. Kasher, P. Tran	██████████																			
Strategy #2: Product Development		Strategy #2: Product Development																			
Formulation/packaging needs	GPU J.R. Richards, G. Hadley	██████████																			
Develop formulation priorities	Core Team J. Kasher	██████████																			
Develop multiple tablets	DPM T. Van Abeele	██████████																			
Develop granules (+ reconst.)	DPM/European Prod. Mgr T. Van Abeele, R. Marsden	██████████																			
Develop short-acting IM	Core Team T. Van Abeele	██████████																			
Develop depot IM	Core Team T. Van Abeele	██████████																			
Pursue other line extensions	GPU/TDP Richards, Hadley, Apathy	██████████																			
Strategy #3: Establish olanzapine as standard of care		Strategy #3: Establish olanzapine as standard of care																			
Clinical trials to differentiate	Core Team C. Beasley, J.R. Richards	██████████																			
Obtain broad package labeling	Core Team C. Beasley, J.R. Richards	██████████																			
Develop HE and QOL	HE L. Genduso, J.R. Richards	██████████																			
Patient Management System	GPU J.R. Richards, G. Hadley	██████████																			
Corporate Communications Plan	GPU J.R. Richards, G. Hadley	██████████																			
Develop plan to redefine standard of care	Core Team/GPU C. Beasley, J.R. Richards	██████████																			
Strategy #4: Market Penetration		Strategy #4: Market Penetration																			
Develop Country specific marketing plans	GPU/Affiliates J.R. Richards, G. Hadley	██████████																			
Global branding strategy	GPU J.R. Richards, G. Hadley	██████████																			
Aggressive pre-launch marketing	GPU J.R. Richards, G. Hadley	██████████																			
Post-launch marketing to gain access	GPU/Affiliates J.R. Richards, G. Hadley	██████████																			
Identify channels of distribution	GPU J.R. Richards, G. Hadley	██████████																			
Evaluate off-label uses and new indications	GPU J.R. Richards, G. Hadley	██████████																			
Strategy #5: Participate in emerging mkts		Strategy #5: Participate in emerging mkts																			
Prioritize emerging markets	Core Team Dickson, Danquist, Ringer	██████████																			
Build corporate presence	GPU/Business Dev. Dickson, Danquist, Ringer	██████████																			
Develop marketing plans	GPU J.R. Richards, G. Hadley	██████████																			
Coord entry with med/mid/reg	Core Team Kasher, Richards, Tran	██████████																			

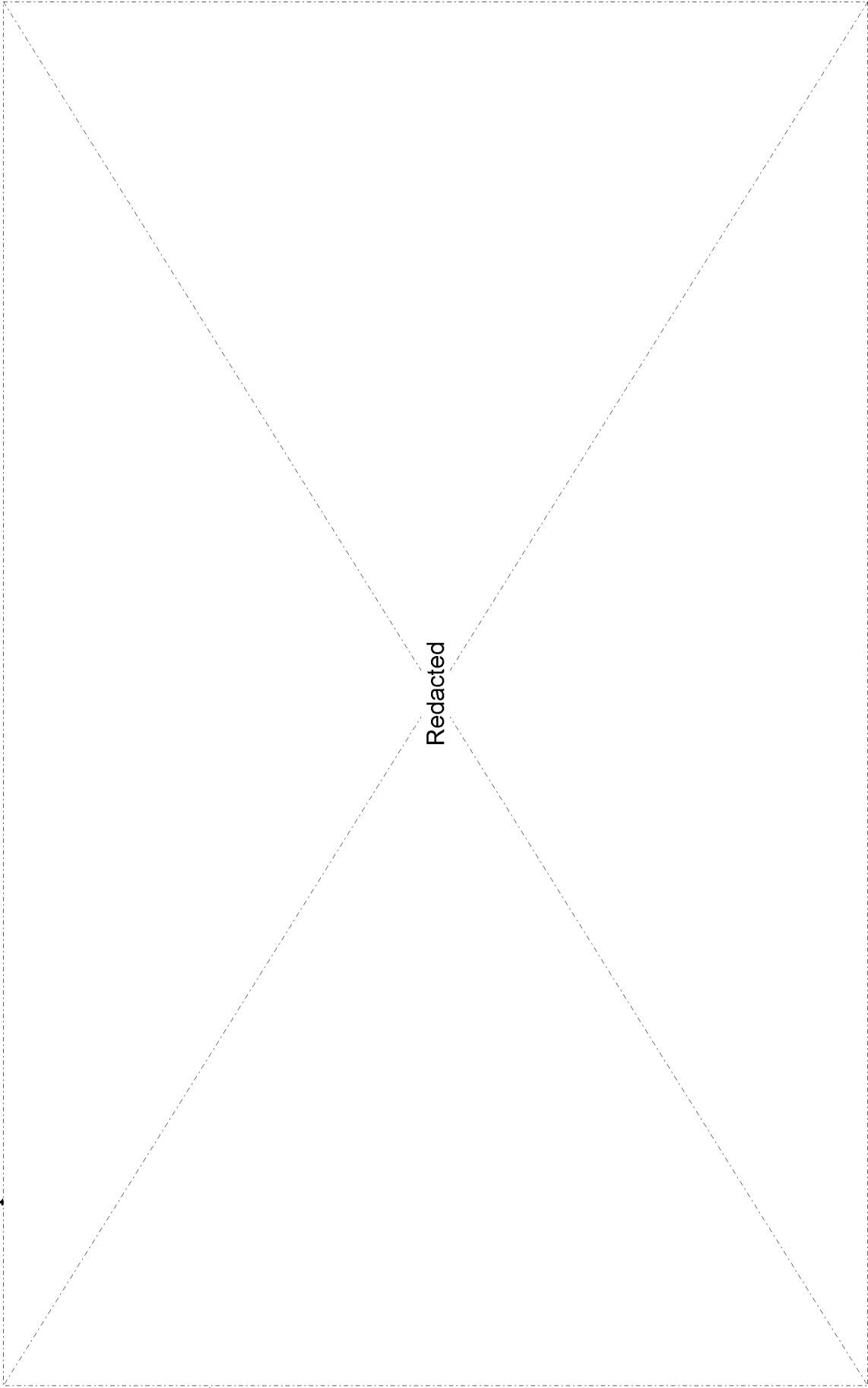
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SECTION SIX

Financial

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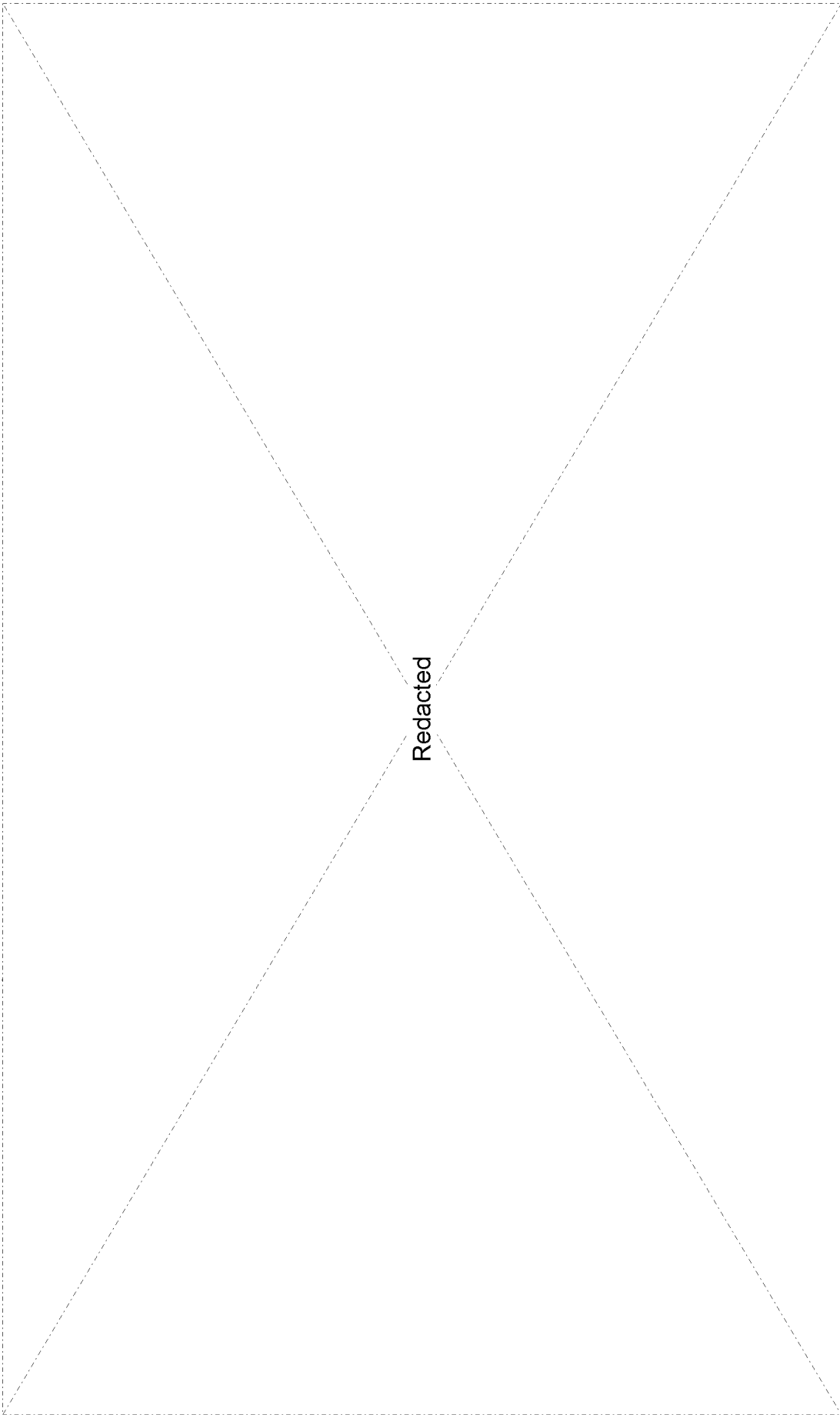
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First Tier GRDs

Efficacy:

- Positive symptoms
- Negative symptoms
- Overall efficacy
- Effect on cognition
- Treatment resistant patients

Safety:

- Side effect profile
- EPS profile
- Seizure potential
- Overdose profile
- Blood dyscrasias
- Weight gain
- Sexual dysfunction
- Stop code side effect letter
 - Clinical trial tables
 - Spontaneous events table
- Drug interaction profile
- Effect on prolactin levels

Clinical:

- Dosing
- Pharmacokinetics (ADME)
- Use in elderly (safety/efficacy/dose)
- Mechanism of action (pharmacology)
- Use in renal failure patients
- Use in hepatic failure patients
- Switching

Comparison:

- Clozapine
- Haloperidol
- Risperidone

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PLEASE RETURN TO: STEVEN J SLOVICK MC648 48/03

October 24, 1995 17:25

To: SLOVICK STEVEN J IVM1
SMITH ANGELA M IVM1
cc: FERGUSON KEVIN J AVAX
SCHMID ROBERT P IVM1

Just wanted to provide you both with a summary of our meeting today.

Re: Process of developing a Tier 2 Global Response Documents List for Medical Information

- 1) Review of First Tier GRD's (Role of Kevin Ferguson in Medical Information)
- 2) Market Research Objective: Gather data from our customers that will help us generate a Second Tier GRD List of Questions

Process: Add an open-ended question (regarding what our customers want to know about Olanzapine) to the end of the Message Testing sequence for the following affiliates: US, Canada, France, UK, Italy, Spain, Netherlands, Australia, Germany (?)

Angela will design an information sheet for the affiliates explaining our objectives, the GRD data collection process and due date - December 1, 1995. Steve will be forwarding this sheet along with the instructions for conducting message testing October 25, 1995.

Thanks again for all your help !

Daphne

RAGSDALE DAPHNE G IVM1

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