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2002 Tactical Plan RISPERDAL® Child and Adolescent Segment

October 9, 2001

Kent Bockes, Product Director, CNS

J-TXCID1053887

EXHIBIT	<u>1028</u>
WIT:	<u>DeLoria</u>
DATE:	<u>2-12-09</u>
Cynthia Vohlken	

PLAINTIFF'S
EXHIBIT
46



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BUSINESS UPDATE (3 slides)



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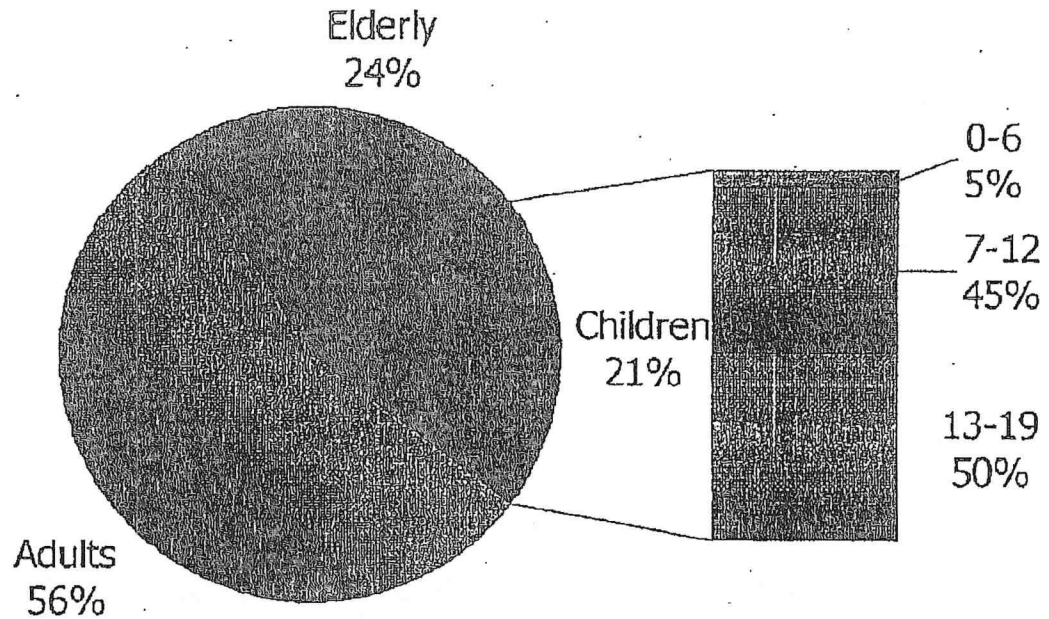
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RISPERDAL Distribution by Patient Age

Child and adolescent patients comprise 21% of Risperdal's overall uses, twice the APS market rate. Half of Risperdal child and adolescent patients are under age 13.



Child and adolescent defined as ages 0-19.
Source: IMS Health, NDTI, MAT 5/01

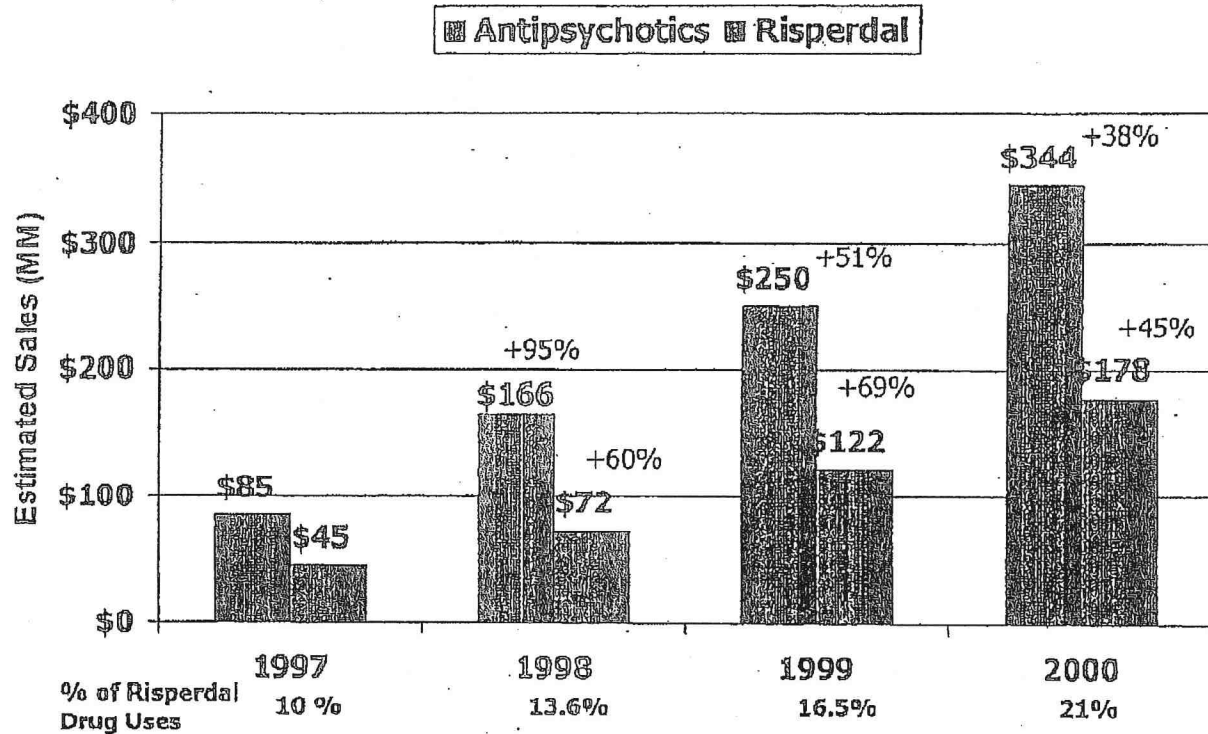
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Antipsychotic Sales for Child and Adolescent Market



Child and adolescent defined as ages 0-19.

Source: IMS Health, NDTI and Retail/Provider Perspective and Internal Sales

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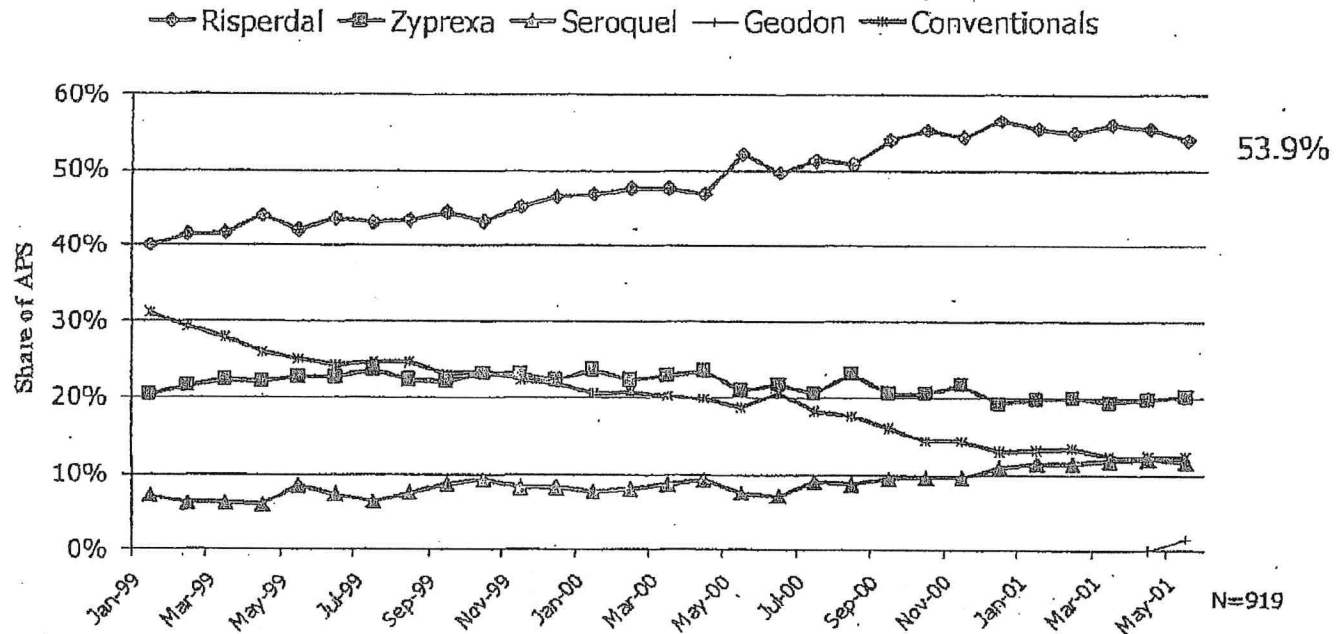
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Antipsychotic Share in Child & Adolescent Market

Risperdal is the leading antipsychotic in the pediatric market, with over a 50% share.



Child and adolescent defined as ages 0-19.

Source: IMS Health, NDTI

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FORECAST REVIEW (3 slides)

- Financials
- Assumptions
- Share Calls

Base/Upside/Downside

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Key Data Available for Dissemination

JRF Generated

- ◆ RIS - USA - 93 (CDMR, aggression)
- ◆ RIS - USA - 97 (CDMR, aggression)
- ◆ RIS - CAN - 19 (CDMR, aggression)
- ◆ RIS - CAN - 20 (CDMR, aggression)
- ◆ RIS - INT - 41 (CDMR, aggression)
- ◆ NIMH Sponsored RUPP Trial (autism, agitation)
- ◆ RIS - BEL - 22 (autism)
- ◆ RIS - BEL - 24 (behavior disturbances)

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KEY STRATEGIES (1 slide)

- ◆ Expand market by increasing awareness and appropriate use of RISPERDAL
- ◆ Develop Child and Adolescent Public Relations and Media Management Plans
- ◆ Differentiate RISPERDAL from other antipsychotics and other therapeutic classes
- ◆ J&J Pharm Sector Strategic Plan Development

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Risperdal Child & Adolescent Tactics by Strategy

Expand Market by increasing awareness & appropriate use of Risperdal	Develop Child & Adolescent PR and Media Management Plans	Differentiate Risperdal from the other APS/ other therapeutic classes
<ul style="list-style-type: none">• AACAP Consensus Guidelines on APS• KOL Advisory Boards• Advisory Strategic Management Network	<ul style="list-style-type: none">• AMA Media Briefing Program• Advocacy Program/ Spokespersons	<ul style="list-style-type: none">• Psych Centers of Excellence• Case Review Network• Excellence in Education Home Study Kit• Audiotape Series – SE Mgmt; Sympt. Mgmt; Dosing• Poster Book (CME)

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Risperdal Child & Adolescent Tactics

- AACAP Consensus Guidelines
- KOL Advisory Boards
- KOL Strategic Management Network
- AMA Media Briefing for Child Mental Health
- Advocacy Sponsored Success Stories Briefing
- Psychiatry Centers of Excellence
- Case Review Network
- Excellence in Education Home Study Kit
- Audio tape Series
- CME Poster Book

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AACAP Consensus Guidelines for APS

Strategy: Expand Market by increasing awareness & appropriate use of Risperdal

Objectives/Description

Development of a psychopharmacology consensus document defining the appropriate use of atypical antipsychotics for diagnostic and symptomatic control of child and adolescent mental illness. This consensus guideline would be developed by an AACAP appointed committee of experts in child and adolescent psychopharmacology.

Audience

Clinicians

Investment

\$ 600,000

Measurement/ROI

Disseminated consensus guidelines (available for all clinicians).
Decrease in inappropriate use/dosing variability as measured by IMS/NDTI audits and market research.

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KOL Advisory Boards

Strategy: Expand Market by increasing awareness & appropriate use of Risperdal

Objectives/Description

Gain insight/understanding of key issues faced by thought leaders.
Receive feedback on our current strategic plans for clinical development, education, and advocacy support through small interactive meetings with key clinicians.

Audience

Opinion leaders in Child and Adolescent Psychiatry.

Investment

\$ 1,600,000

Measurement/ROI

Refined plans for clinical development, educational initiatives and advocacy interaction. New ideas for EMRP initiatives which enhance our key safety/efficacy messages.

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Advisory Strategic Management Network

Strategy: Expand Market by increasing awareness & appropriate use of Risperdal

Objectives/Description

A data base management system which allows instant access to a strategic view of our advisor activities. This network will allow a mechanism for continuous follow-up with our advisors to maximize our feedback/strategic input from these key opinion leaders.

Audience

Opinion leaders in Child and Adolescent Psychiatry.

Investment

\$ 100,000

Measurement/ROI

Rapid turnaround time for input from advisors on key posters, publications, and market research projects which allow for enhancements/refinements to our strategic plan. Advisor satisfaction/input will also be a key measurement.

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AMA Media Briefing Program

Strategy: Develop Child & Adolescent PR and Media Management Plans

Objectives/Description

A fair balanced overview of the child and adolescent mental health clinical data/issues provided by the AMA to medical journalists who regularly report on health issues in national periodicals.

Audience

National Audience of clinicians, educators, parents, governmental and public policy decision makers interested in children's health issues.

Investment

\$ 150,000

Measurement/ROI

Number of fair balanced publications citing issues related to children's mental health. Advocacy group mobilization to increase dialogue/public discussions generated by these publications. Decrease in number of factually incorrect stories dealing with children's mental health.

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Advocacy Programs/Spokespersons

Strategy: Develop Child & Adolescent PR and Media Management Plans

Objectives/Description

Identify advocacy family success stories in organizations such as CABF, NAMI, and Cure Autism Now. Support these organizations as they use the dissemination of these success stories to further the cause of children's mental health.

Audience

Advocacy groups in schizophrenia, bipolar disorder, and autism.

Investment

\$ 250,000

Measurement/ROI

Increased awareness/coverage of families who have successfully reintegrated children with mental illness. Increased public policy dialogue regarding reimbursement for childhood mental illness.

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Psychiatric Centers of Excellence

Strategy: Differentiate Risperdal from other APS/other therapeutic classes

Objectives/Description

CME programs held at nationally recognized child and Adolescent psychiatric centers. Each hosting center will provide an interactive educational forum to help clinicians deal with key child and adolescent treatment issues.

Audience

Key teaching hospitals, clinicians.

Investment

\$ 350,000

Measurement/ROI

CME Program - measurement restricted to attendee satisfaction, providing institution's feedback, CME redemptions, attendance and lost per attendee.

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Case Review Network

Strategy: Differentiate Risperdal from other APS/other therapeutic classes

Objectives/Description

CME program designed to provide participants with actual case study learning facilitated by nationally recognized thought leaders.

Participants will then be asked to provide their own cases which can be used to develop future case study programs.

Audience

Clinicians.

Investment

\$ 100,000

Measurement/ROI

CME Program - measurement restricted to attendee/participant/facilitator satisfaction and CME redemptions, attendance and lost per attendee.

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Excellence in Education Home Study Kit

Strategy: Differentiate Risperdal from other APS/other therapeutic classes

Objectives/Description

CME program designed to provide a comprehensive self study package for clinicians interested in enhancing their knowledge of key issues in child and adolescent practice management. Kit will include: CME Monographs; CME Textbooks; Interactive CD-Roms; and all (CE) pre/post tests.

Audience

Clinicians.

Investment

\$ 500,000

Measurement/ROI

CME Program - measurement restricted to customer satisfaction and CME redemptions, attendance and lost per attendee.

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Audio Tape Series

Strategy: Differentiate Risperdal from other APS/other therapeutic classes

Objectives/Description

CME audio tape series designed to educate clinicians about important safety, efficacy, and dosing issues related to child and adolescent psychopharmacology. Programs also allow physicians the opportunity to ask specific questions and access the programs at their own convenience.

Audience

Clinicians.

Investment

\$ 300,000

Measurement/ROI

CME Program - measurement restricted to customer satisfaction and CME redemptions, attendance and lost per attendee.

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CME Poster Book

Strategy: Differentiate Risperdal from other APS/other therapeutic classes

Objectives/Description

CME accredited compilation of posters presented at key medical meetings. All posters relevant to child and adolescent psychopharmacology would be included in one source book for clinician education and CME credit.

Audience

Clinicians.

Investment

\$ 125,000

Measurement/ROI

CME Program - measurement restricted to customer satisfaction, unsolicited requests for materials, and CME redemptions, attendance and lost per attendee.

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Risperdal Child & Adolescent PME's

Advertising		50,000
• Agency Fees	50,000	
Medical Education		5,257,000
• Ad Boards	1,700,000	
• Symposia	600,000	
• CME	2,057,000	
• Supplements	750,000	
• Reference Reprints	100,000	
Publications		1,100,000
• Abstracts/Posters	500,000	
• Consensus Guidelines	600,000	
Public Relations		500,000
• AMA Media	150,000	
• Advocacy Forums	350,000	
Grants		150,000
Other		375,000
• Market Research	200,000	
• Consultants	50,000	
• Preceptorships	25,000	
• J&J Pediatric Meeting	100,000	
Total		<u>\$7,432,000</u>

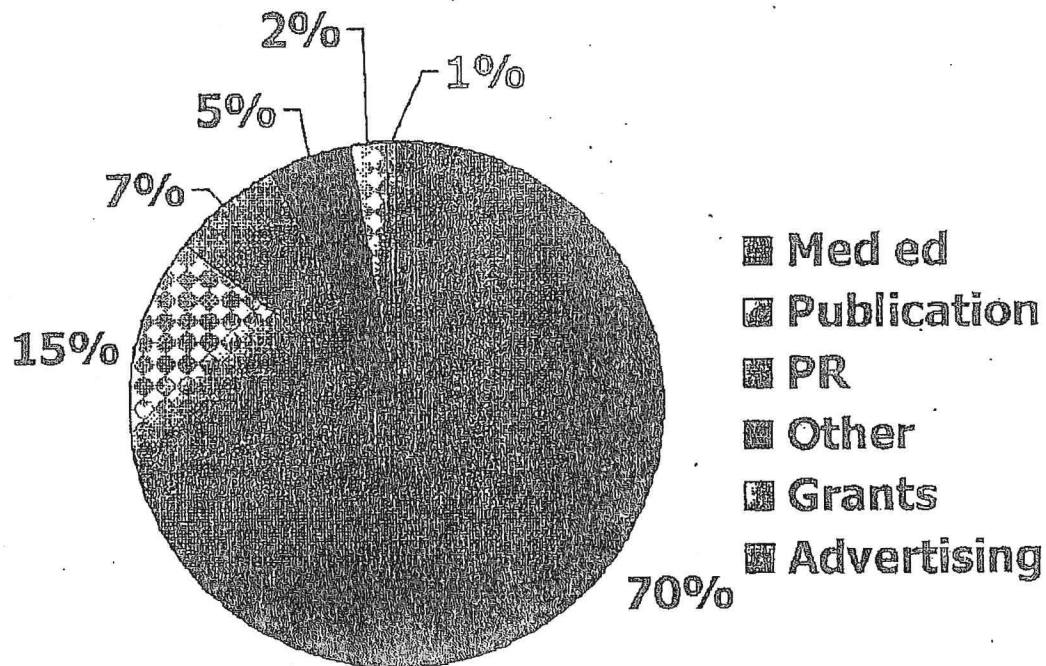
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Risperdal Child & Adolescent PME's



Total = 7,432,000

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PME (Regional PMEs by sales force 1 slide)



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2002 Risperdal Child & Adolescent Execution and Tracking Calendar

Tactic & Target Audience	Q1 Milestone/Result	Q2 Milestone/Result	Q3 Milestone/Result	Q4 Milestone/Result	Target Result/Completion Date
Tactic: AACAP Consensus Guidelines for APS Target Audience: Clinicians	Consensus Group Identification Meeting	Guideline Development	Guideline Draft Revision	Guidelines Adopted	Target Date AACAP 2002 4Q Meeting
Tactic: KOL Advisory Boards Target Audience: OL in C&A Psychiatry	National Ad Boards HOV's	Regional Ad Board HOV's	Regional Ad Board HOV's	Regional Ad Boards HOV's	All Programs complete Nov 2002
Tactic: Advisory Strategic Management Network Target Audience: OL in C&A Psychiatry	Data Base Developed - Jan Content for Dissemination Finalized - Feb	1 st wave of communication sent/feed back measured	2 nd wave of communication sent/feed back measured	3 rd wave of communication sent/feed back measured AACAP Review sent	Dec. 2002
Tactic: AMA Media Briefing Program Target Audience: National Audience	March Deployment				1Q02
Tactic: Advocacy Programs/Spokespersons Target Audience: Advocacy Groups	Formal Meetings identification of targets NAMI, CBF, CAN	Advocacy identification of families	Story disseminated	Story disseminated	4Q02

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2002 Risperdal Child & Adolescent Execution and Tracking Calendar

Tactic/ Target Audience	Q1 Milestone/ Result	Q2 Milestone/ Result	Q3 Milestone/ Result	Q4 Milestone/ Result	Target Result Completion Date
Tactic: AACAP Psych Centers of Excellence Target Audience: Key teaching Hospitals/Clinicians	Sites identified Programs developed	Accreditation invites to program 1 Completion of program 1	Program 2/3 invites, complete CE Processed	Program 4/5 invites, complete CE Processed	4Q02 & CE processing Ongoing
Tactic: Case review network Target Audience: Clinicians	Facilitators identified, Cases identified, Accreditation approved	Results Published/ Disseminated • Audio/video • Text +CE Process	Results Published/ Disseminated • Audio/video • Text +CE Process	Next case series Facilitators Identified Cases identified	Program 1 3Q02- Program 2 started 4Q02
Tactic: Excellence in Education Home Study Kit Target Audience: Clinicians	Content develop - Mar	Program Accreditation - June	Program Production completion - Sept.	Program Distribution - Oct.	4Q02 with CE processing ongoing
Tactic: Audiotape series Target Audience: Clinicians	March: Facilitator chosen and content development finished	Program accredited - Apr. Program distributed - May	Program distributed & 24hr. availability, CE processed	24hr. availability CE processed	3Q02 live program complete, 4Q02 24 available & CE processing ongoing
Tactic: CME Poster Book Target Audience: Clinicians	Accreditation body determined	Content finalized production completed	Book disseminated CE Processed	Book disseminated CE Processed	4Q02 Book Dissemination CE processing ongoing

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CRITICAL SUCCESS FACTOR REVIEW

(1 slide)



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Risperdal Child & Adolescent Critical Success Factors

- ◆ Data Needed to Demonstrate:
 - Long Term Safety
 - Efficacy Across Diagnosis
 - Efficacy Across Symptoms
- ◆ Education Necessary With the Following Key Groups:
 - Clinicians
 - KOL's
 - Press
 - Advocacy Group Partnerships
- ◆ FDA Clarification

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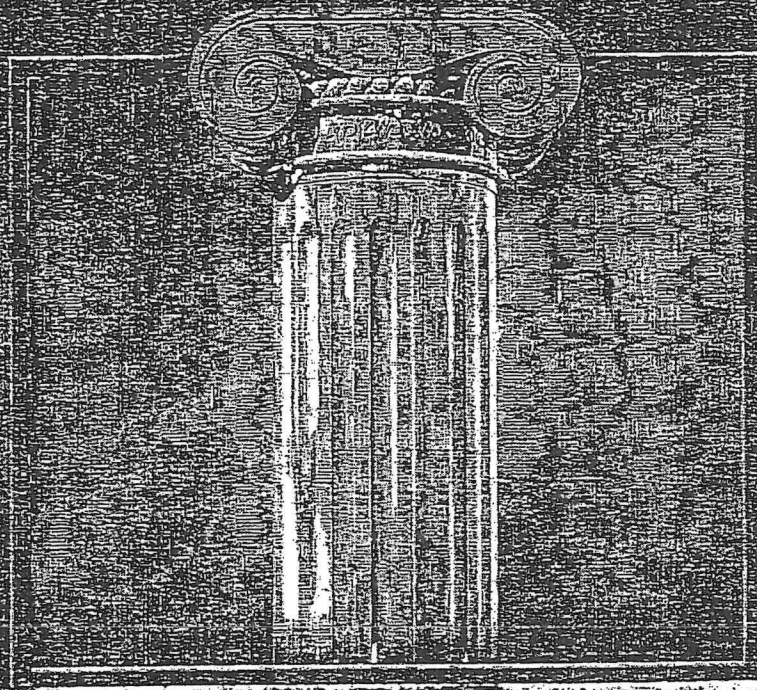
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BACK-UP

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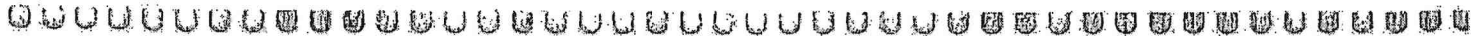
SALES TRAINING



CNS

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ed. Calm Motivation.

More than 9 years of demonstrated safety and tolerability

MANAGEABLE SAFETY PROFILE

- ▶ Low weight gain: 3.1 lb average weight gain over 1 year*
- ▶ Low risk of diabetes (0.2%)** and diabetic ketoacidosis (DKA)
- ▶ Low risk of hyperlipidemia: <0.1%
- ▶ Low incidence of TD: 0.3%–0.6%***

EXCELLENT TOLERABILITY

- ▶ Minimal reversible movement disorders (EPS) at recommended doses**
 - † Dose-response relationship; low doses are correlated with a low incidence of reversible movement disorders (EPS)
- ▶ Prolactin-related side effects comparable to olanzapine in a double-blind comparative trial (N=377)**
- ▶ Low incidence of excessive sedation
- ▶ Low incidence of orthostatic hypotension
 - Orthostatic hypotension may lead to falls

*Based on additional safety evaluations on page 8
**Data on file by AstraZeneca

Risperdal
RISPERIDONE
Helping You Live Around.

RISPERDAL® (risperidone)

CNS Sales Aid Primer

Page 9

Why This Information Is Important

- Sets up the idea of putting these issues into perspective with regard to the risk/benefit ratio of RISPERDAL versus other atypicals.
- A variety of safety and tolerability side effects associated with atypicals are of particular concern in this patient population.
 - Weight gain is still an issue in the atypical class, most notably with olanzapine
 - The low weight gain exhibited by RISPERDAL is in contrast to the increased weight gain observed in clinical trials with olanzapine.
 - Diabetes is another serious concern with atypicals that has been well documented in a number of case studies
 - Olanzapine is associated with a significant risk of diabetes and has also been linked to conditions such as diabetic ketoacidosis (DKA) and diabetic coma, irrespective of weight gain.
 - Diabetes and other metabolic complications are not readily apparent, require testing, and may be difficult to manage
- RISPERDAL has been associated with a low risk of diabetes and DKA
 - Olanzapine has also been linked to other metabolic disorders that require monitoring, such as hyperlipidemia, which increases the risk of cardiovascular disease.
 - RISPERDAL is associated with a low incidence of hyperlipidemia

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ed. Calm Motivation.

More than 9 years of demonstrated safety and tolerability

MANAGEABLE SAFETY PROFILE

- ▶ Low weight gain: 5lb average weight gain over 1 year¹
- ▶ Low risk of diabetes (0.2%)² and diabetic ketoacidosis (DKA)
- ▶ Low risk of hyperlipidemia: <0.1%
- ▶ Low incidence of TD: 0.3%-0.6%³

EXCELLENT TOLERABILITY

- ▶ Minimal reversible movement disorders (EPS) at recommended doses⁴
 - Dose-response relationship: low doses are correlated with a low incidence of reversible movement disorders (EPS)
- ▶ Prolactin-related side effects comparable to olanzapine in a double-blind comparative trial (N=322)⁵
- ▶ Low incidence of excessive sedation
- ▶ Low incidence of orthostatic hypotension⁶
 - Orthostatic hypotension may lead to falls

Risperdal
RISPERIDONE
Helping Turn Lives Around

1. Data on file at Bristol-Myers Squibb. 2. Data on file at Bristol-Myers Squibb. 3. Data on file at Bristol-Myers Squibb. 4. Data on file at Bristol-Myers Squibb. 5. Data on file at Bristol-Myers Squibb. 6. Data on file at Bristol-Myers Squibb.

RISPERDAL® (risperidone)

CNS Sales Aid Primer Page 9 cont.

- Use the term *reversible movement disorders (RMD)* instead of EPS to convey that this may be a reversible tolerability concern and to distinguish it from the more devastating persistent movement disorders, such as tardive dyskinesia (TD)
 - TD is usually a persistent movement disorder and one that RISPERDAL rarely causes
- At lower doses, RISPERDAL exhibits low incidences of RMD
 - Physicians who see RMDs with RISPERDAL may have started the patient on too high a dose or titrated up too quickly
 - Flexible dosing options with RISPERDAL allow physicians to achieve efficacy while minimizing RMDs
- Unlike many safety concerns and tolerability issues, physicians are alerted quickly to RMDs and can react appropriately to best manage patient outcomes
- Although RISPERDAL had a significant increase in prolactin levels in a double-blind, comparative trial versus olanzapine, RISPERDAL showed similar rates of prolactin-related side effects
 - Supports the fact that increased prolactin levels may not be associated with prolactin-related side effects
- Encourages physicians to prescribe RISPERDAL over olanzapine due to:
 - Comparability on this side-effect issue and superiority across a range of other side effects
 - Superior efficacy demonstrated in the treatment of anxious and depressive symptoms associated with schizophrenia in a head-to-head trial at Week 8

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Interested Focused Calm Motivation

Check in with your customers to proactively discuss Risperdal's safety profile

Doctor, do you have any questions or concerns about (CAE, EPS, TD)?

Risperdal
 Risperidone Tablets and Oral Solution

Interested Focused Calm Motivation

Risperdal offers you and your patients an excellent safety profile with less weight gain vs. Zyprexa and minimal sedation*

What is the benefit of this selling feature?

Risperdal
 Risperidone Tablets and Oral Solution

Interested Focused Calm Motivation

Doctor, Risperdal offers your patients control over a broad range of symptoms of schizophrenia. Risperdal is also available in the largest number of delivery systems providing many options for your patients

Remember M-Tab is the acute setting

Check in today! Doctor, have you discussed the advantages of Risperdal's M-Tab in practice? Risperdal for patients that present with symptoms such as associated with schizophrenia (e.g., depression, insomnia, anxiety, etc.)

Risperdal
 Risperidone Tablets and Oral Solution

Interested Focused Calm Motivation

Substantial cost savings*

Risperdal
 Risperidone Tablets and Oral Solution

Interested Focused Calm Motivation

Key Feature: Risperdal provides significantly more effective therapy with important safety and tolerability advantages for treating the mood and anxiety symptoms associated with schizophrenia


Risperdal
 Risperidone Tablets and Oral Solution

Sales Aid Exercise

- Break into 5 groups
- Each group takes one spread
 - Opening and Closing
 - Receptor Binding Spread
 - Low dose Spread
 - Conley Spread
 - Safety Spread
 - Dosing and Cost Spread
- Identify key messages and role play spread


Risperdal
 Risperidone Tablets and Oral Solution

**CHILD & ADOLESCENT
PHYSICIANS**

RISPERDAL 


Child & Adolescents

- Can be covered by all CNS reps
- Provide treatment to patients who are under the age of 18
- Most are diagnosed with a "Behavioral Disorder" or a "Mood Disorder"
- Can see initial stages of psychosis
- Provide therapy for children and families
- Generally paid through private insurance

RISPERDAL 


Child & Adolescents

- Key Players
 - Psychiatrist
 - Social Worker
 - Psychologist
 - Family Therapist
- Key Areas
 - Teaching Hospitals, State Hospitals, and Private Psychiatric Hospitals may have specific units
 - Outpatient (CMHC, Private Practice)
 - Private Residential Homes

RISPERDAL 


Child & Adolescents

- Key Issues
 - NO INDICATION
 - Fear of using "antipsychotics"
 - Difficult to treat - diagnosis often unclear
- Key Strategies
 - Sell on *symptoms* not diagnosis
 - Utilize Medical Services for studies
 - Develop relationships now - key for future


RISPERDAL 

Child & Adolescents

- POSITION RISPERDAL AS FIRST LINE
- GAIN SWITCHES FROM COMPETITION
- BE A RESOURCE TO THE C&A
PSYCHIATRISTS
 - Medical Services requests
 - Samples/Coupons
 - CME Programs - Teletopics/DLN

RISPERDAL 

**GERIATRIC
PSYCHIATRISTS**

RISPERDAL 

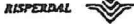
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GERIATRIC PSYCHIATRISTS

- Covered by ElderCare
 - Partner with both M- and I-Reps
- Rotate through various settings - Key Areas
 - Nursing Homes
 - Teaching/Community Hospitals
 - State Hospitals
 - Private Practice
- Provide services to elderly patients who suffer with varying diagnoses
 - Alzheimer's
 - Dementia
 - Psychosis
 - Depression



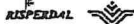
GERIATRIC PSYCHIATRISTS

- Key Issues
 - Not specifically indicated for dementia
 - Geriatric patients can be medically compromised
 - May still be unsure of dosing schedule
- Key Strategies
 - Dosing is key - less is better
 - Sell on *symptoms* not on diagnosis
 - No anticholinergic or QT prolongation
 - Partner with ElderCare reps on high prescribers



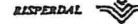
GERIATRIC PSYCHIATRISTS

- POSITION RISPERDAL AS FIRST LINE
- GAIN SWITCHES FROM COMPETITION
- BE A RESOURCE TO THE GERIATRIC PSYCHIATRIST
 - FDAMA Approved Reprints
 - Medical Services
 - Inservices



Summary

- Always deliver the core message - no matter what setting
- Focus on specific symptoms
- Utilize *all* resources that are available
 - Sales Aid
 - Patient Assistance Program
 - FDAMA Reprints
 - Inservice Opportunities
 - Medical Services
 - Speaker Programs
- Determine need at each setting and tailor your calls to their needs



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Probes

- Do you screen for hyperglycemia/diabetes?
- Have any of your patients developed diabetes or any lipid abnormalities on any of the atypicals?
- What precautions do you take if you have a patient who has a higher risk of developing diabetes? (family history, etc.)

Tools to Use

- Sales Aid
 - 0.2% in double-blind + open-label trials (n=2607)
 - Minimal Case Reports (3 reported cases to date)
- Koro Reprint
- Gianfrancesco Reprint
- Teletopics on metabolic abnormalities

"RISPERDAL Causes Prolactin Increases"

Probes

- Approximately how many patients have you treated with RISPERDAL?
 - How often have you seen prolactin-related side effects with your patients?
- Are you seeing actual prolactin-related side effects?
- Is the side effect you are seeing actually related to prolactin increases, or specifically to RISPERDAL?
- What do you do if you see prolactin-related side effects?
- What is your concern for the long term?

Tools to Use

- Sales Aid
 - Conley
 - 9 Years of Experience in over 51 million prescriptions worldwide
- Medical Services

"RISPERDAL Is Not Sedating Enough"