

# RISPERDAL Child and Adolescent Market

Business Plan

July 2001

Presented by:

Kent Bockes, Product Director, CNS

Paul Mullen, Manager, Mkt Research

Ramy Mahmoud, Group Director, CNS Medical Affairs

Subject to Legal and Regulatory Review

**PLAINTIFF'S  
EXHIBIT**

20



# Report of the Surgeon General's Conference on Children's Mental Health

"The burden of suffering experienced by children with mental health needs and their families has created a health crisis in this country".

"Children and families are suffering because of missed opportunities for prevention and early identification, fragmented services, and low priorities for resources. Overriding all of this is the issue of stigma, which continues to surround mental illness".

David Satcher, MD, PhD  
United States Surgeon General

Sept. 18&19, 2000

Subject to Legal and Regulatory Review



# RISPERDAL

## Child and Adolescent Goals

- Remain the gold standard in the C&A market by being recognized as the APS with the strongest clinical efficacy and safety data.
- Ensure that clinicians recognize the appropriateness of antipsychotic therapy for this market segment.
- *Serve as a springboard for a J&J Pediatric psychopharmacology franchise.*

Subject to Legal and Regulatory Review

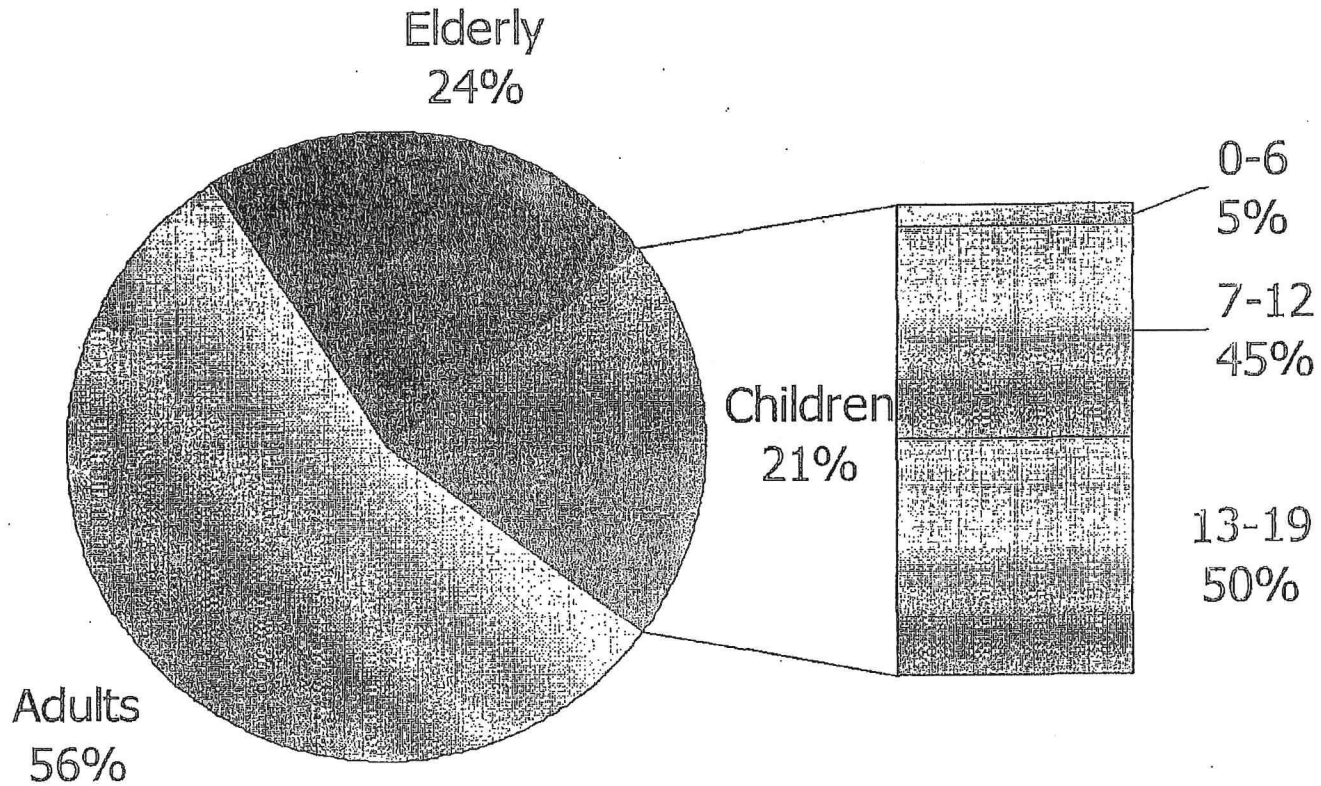




# RISPERDAL

## Distribution by Patient Age

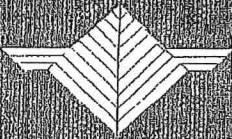
Child and adolescent patients comprise 21% of Risperdal's overall uses, twice the APS market rate. Half of Risperdal child and adolescent patients are under age 13.



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

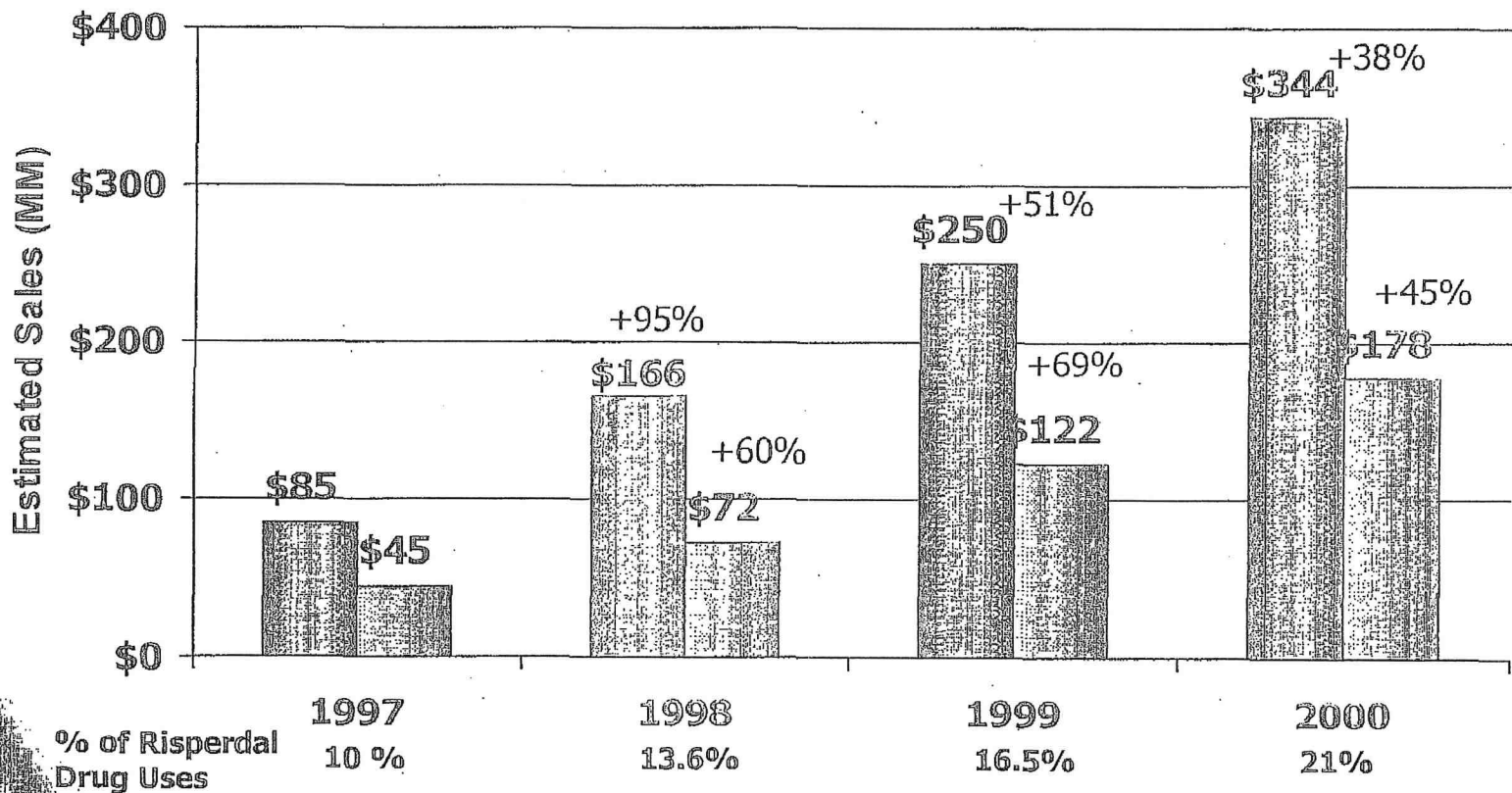
Subject to Legal and Regulatory Review





# Antipsychotic Sales for Child and Adolescent Market

■ Antipsychotics ■ Risperdal



Child and adolescent defined as ages 0-19.

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

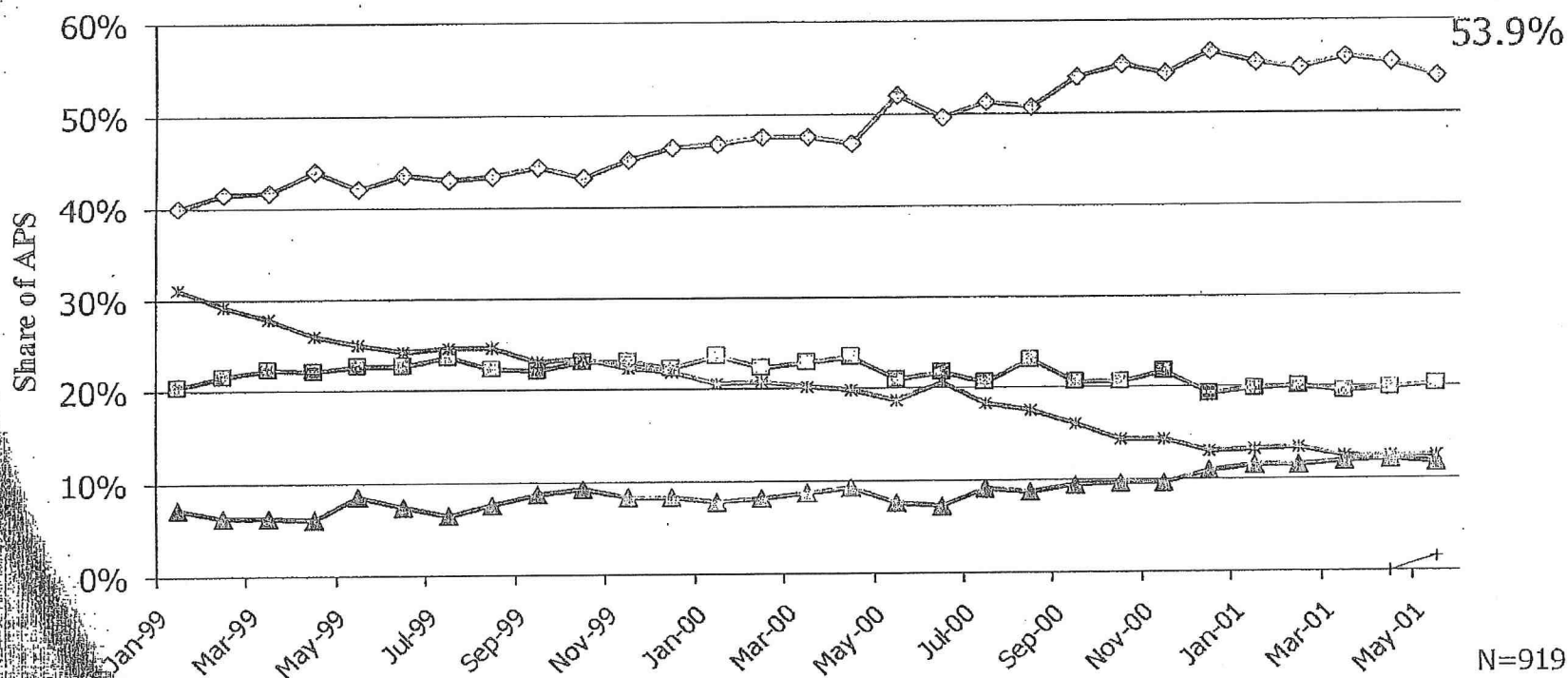
Subject to Legal and Regulatory Review



# Antipsychotic Share in Child & Adolescent Market

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

◆ Risperdal   ■ Zyprexa   ▲ Seroquel   + Geodon   \* Conventionals



Child and adolescent defined as ages 0-19.

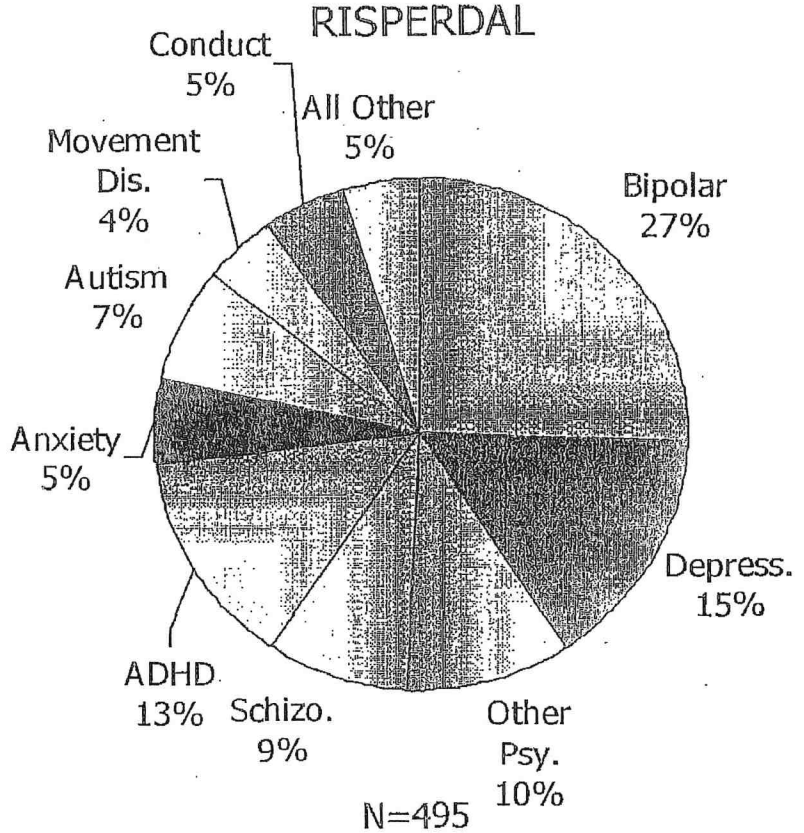
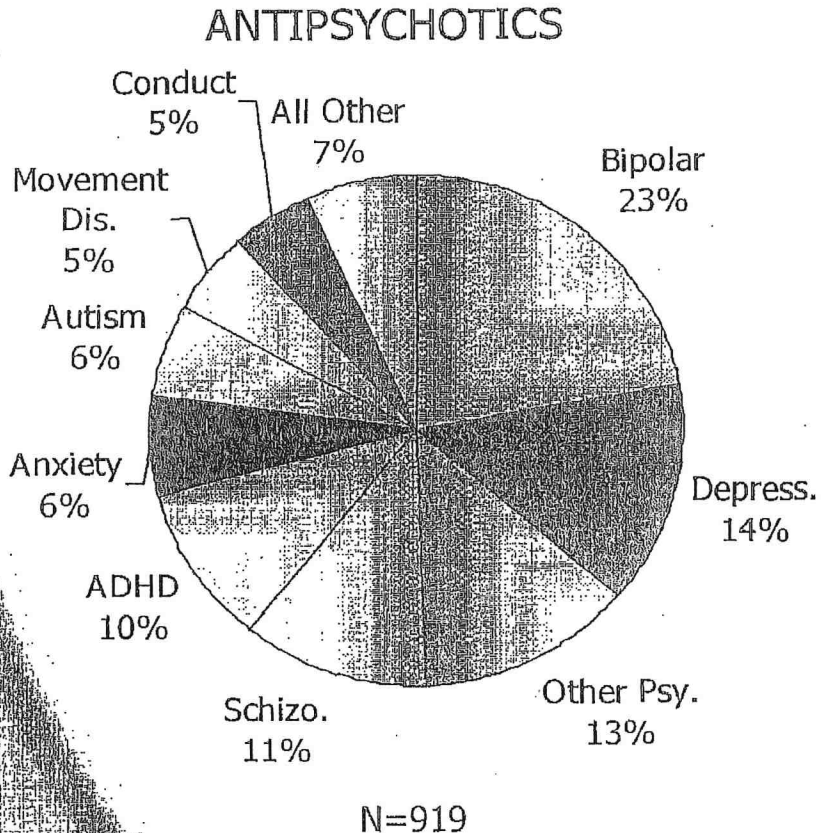
Source: IMS Health, NDTI

Subject to Legal and Regulatory Review



# Antipsychotic Use in Child and Adolescent Patients

Antipsychotics and Risperdal are used to treat a variety of C&A patients. Schizophrenia accounts for only 9% of Risperdal drug use.



Child and adolescent defined as ages 0-19.

Source: IMS Health, NDTI, MAT 5/01

Subject to Legal and Regulatory Review





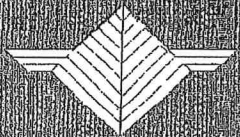
## Use of Antipsychotics Symptoms vs. Diagnosis

*"I want to see symptom suppression. Diagnosis is irrelevant initially. Symptoms are the driving force of treatment modality. Diagnosis takes time to gather information from several resources, and symptoms must be treated in that time." (GEN PSYCH)*

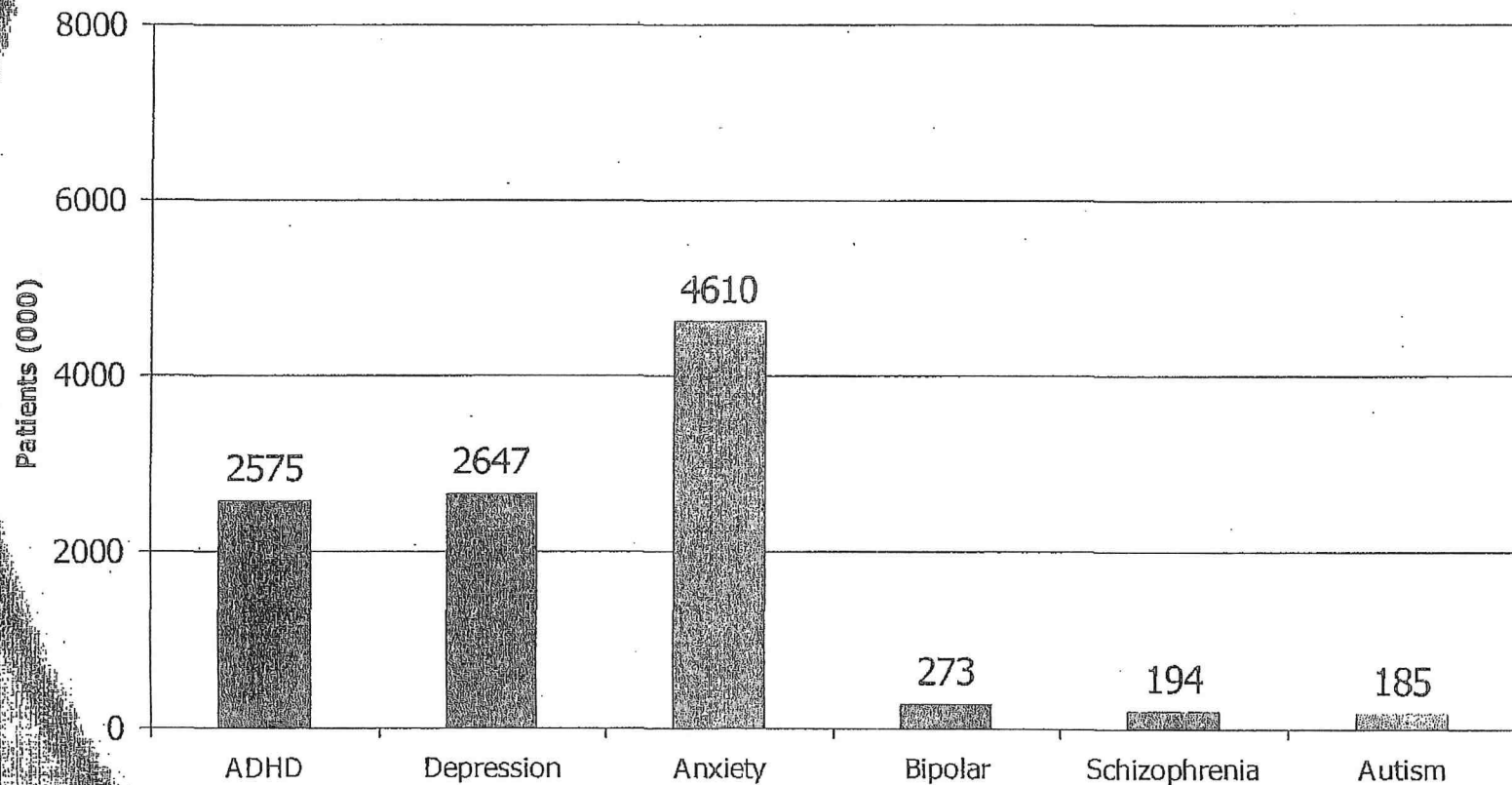
*"In children, sometimes you have more than one diagnosis. So the clinical picture is not crystallized in a clear way. The lines of delineation may not be 100% clear, because children can't express themselves, and families present it differently. Therefore, symptoms are what stand out. . . what you hear from extended caregivers." (CHILD PSYCH)*

RISPERDAL: Opportunity Analysis - Child and Adolescent Patients May 2001 n=101

Subject to Legal and Regulatory Review



# Prevalence of Key Child and Adolescent Markets



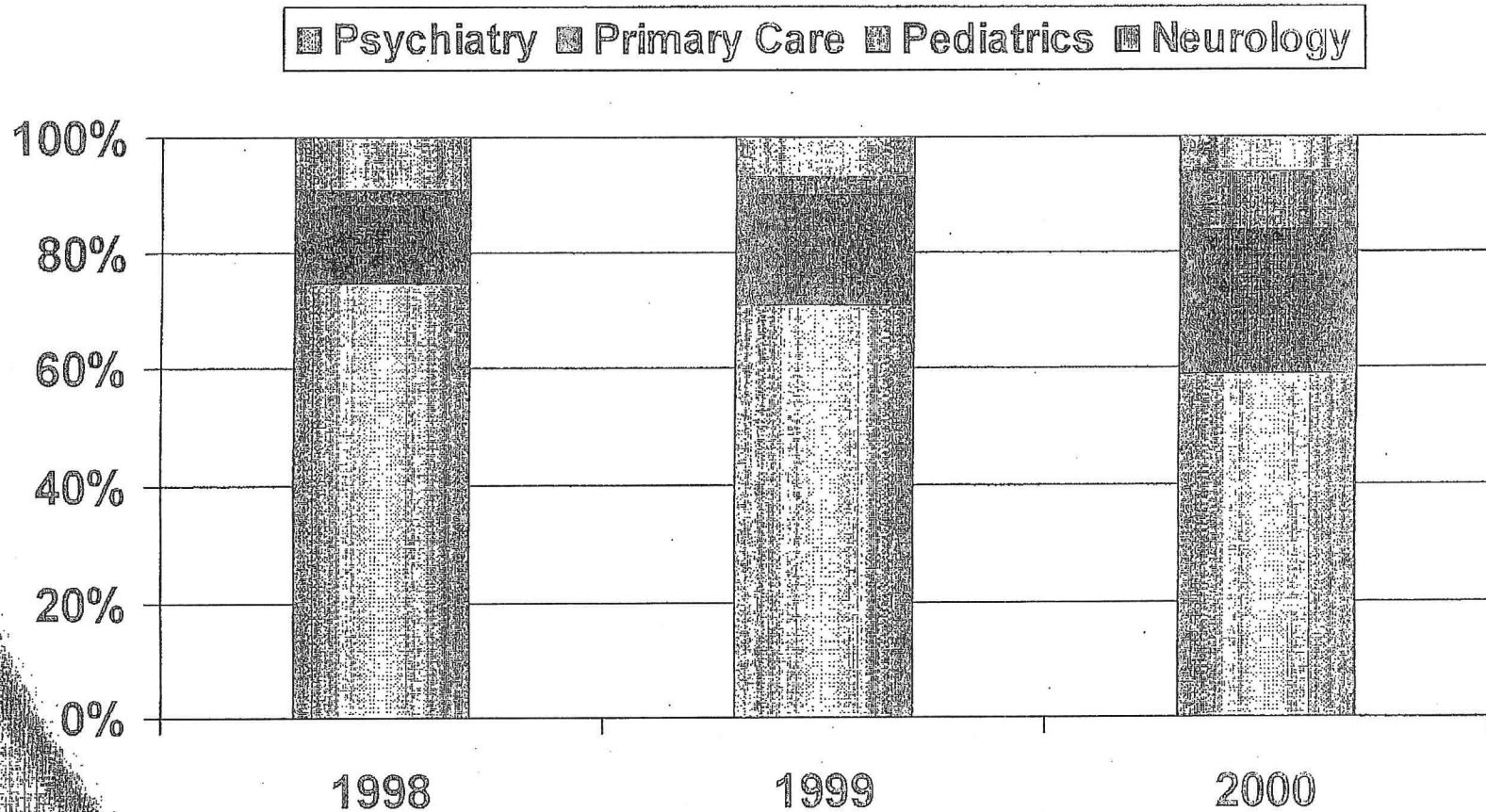
Source: Report of the Surgeon General's Conference on Children's Mental Health, Epidemiology Studies

Child and adolescent defined as ages 0-19.

Subject to Legal and Regulatory Review



# Child & Adolescent Antipsychotic use by specialty



Child and adolescent defined as ages 0-19.

Source: IMS Health, NDTI, Full Year 2000

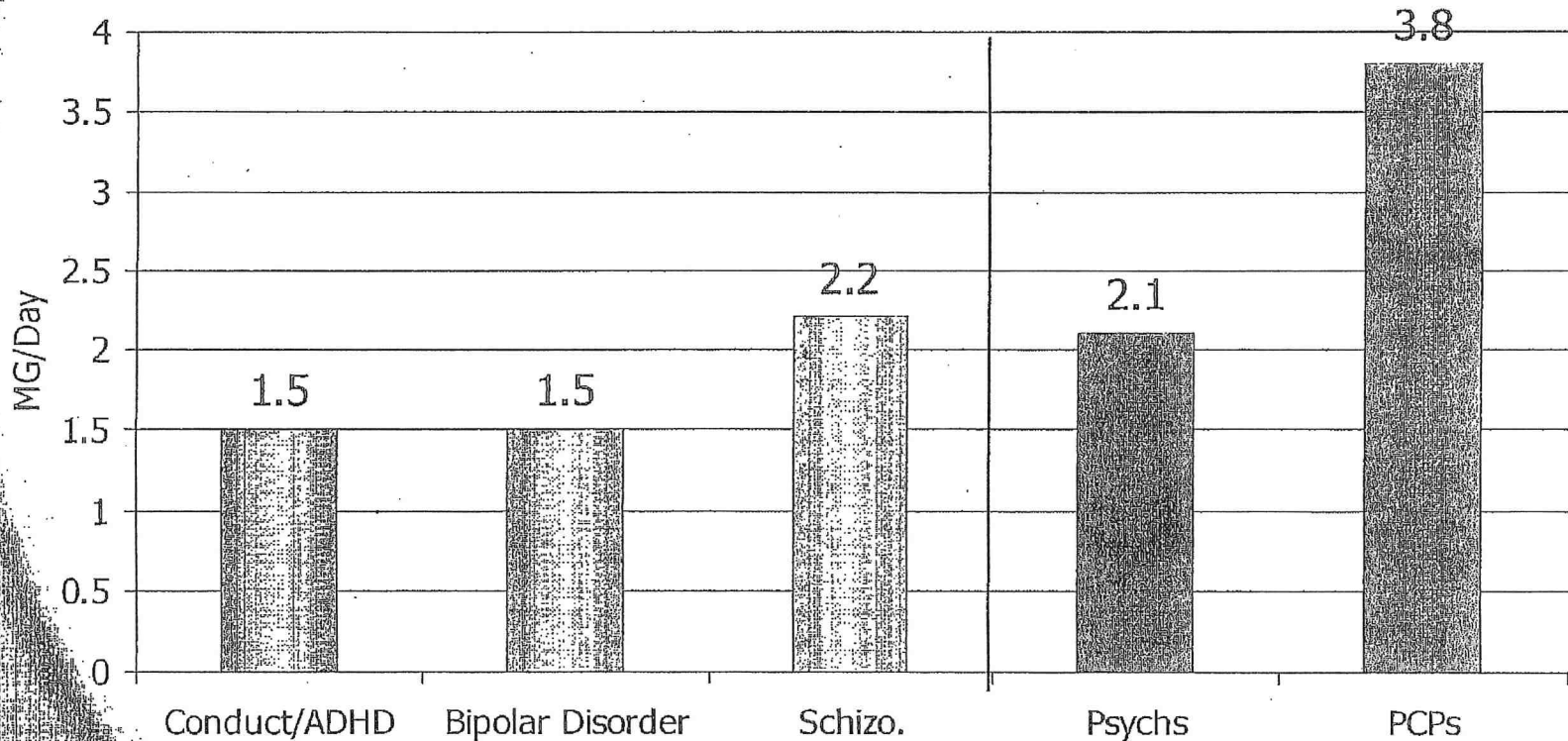
Subject to Legal and Regulatory Review





# Child & Adolescent Dosing of Risperdal

The average Risperdal dose in pediatric patients is 1.7 mg/day, PCPs who treat C&A patients report higher dosing than Psychs.



Child and adolescent defined as ages 0-19.  
Source: IMS Health, NDTI, Full Year 2000

Source: Risperdal Annual Tracking Study,  
May 2001

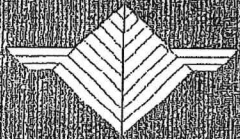
Subject to Legal and Regulatory Review



# Child & Adolescent Market Summary

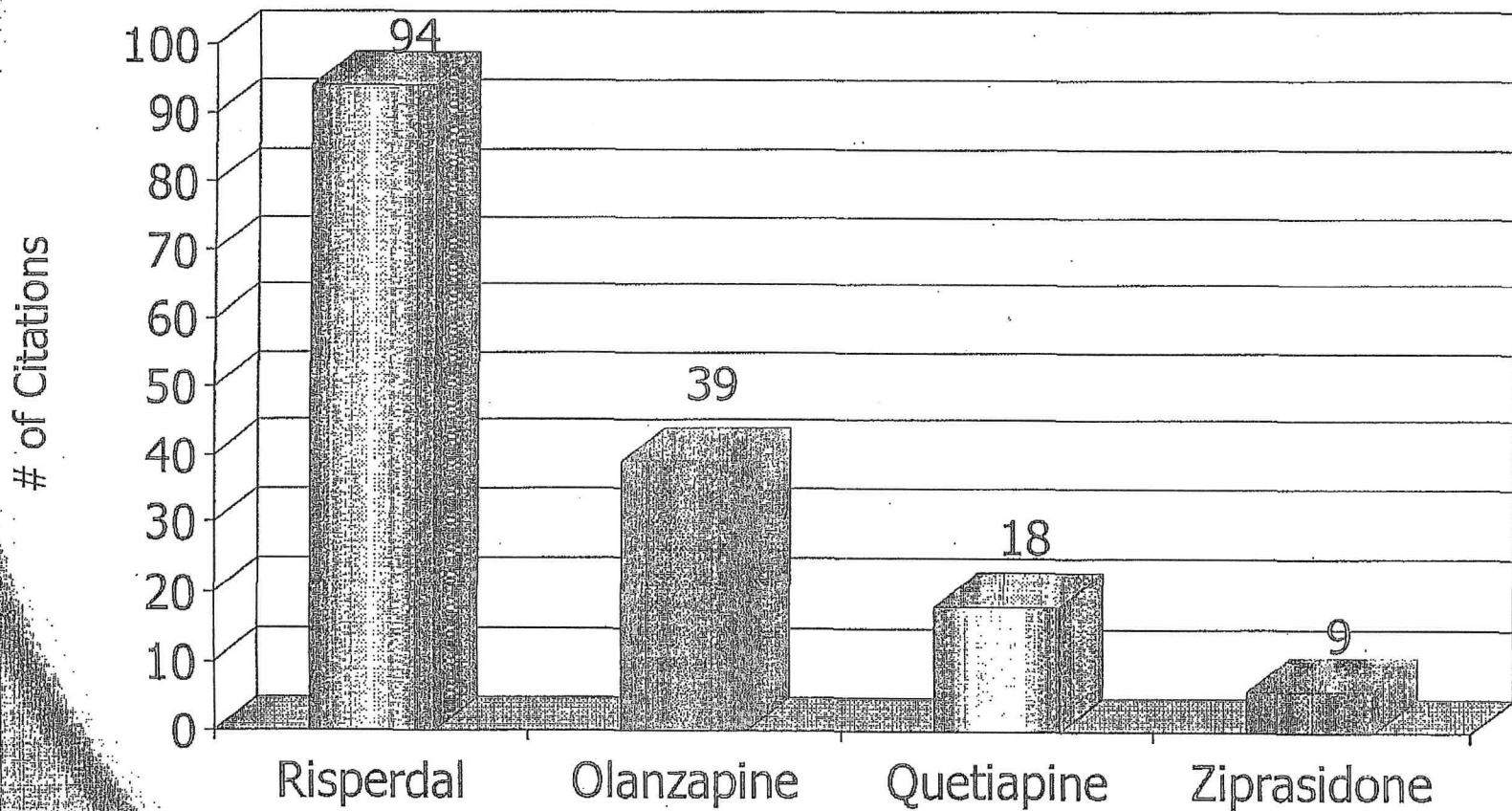
- Child & adolescent market is large and growing
  - 2000 C&A estimates: Risperdal \$178MM, APS Class \$344MM
  - Risperdal C&A TRxs are growing in excess of 50% annually
  - high prevalence across a number of disease states
- APS are used to treat a variety of conditions
  - Decision to treat with APS is based on symptom control rather than diagnosis (hallucinations, aggression)
  - APS have low penetration in the largest markets
- PCPs and Peds are an increasing prescriber base
  - Education is critical in this audience, given the low self-reported knowledge of antipsychotics
- Risperdal is the antipsychotic market leader
  - However, there is increasing competitive focus from Zyprexa, Seroquel, and Geodon

Subject to Legal and Regulatory Review



# Child & Adolescent Citations in Pediatric Journals

■ Risperdal ■ Olanzapine □ Quetiapine ■ Ziprasidone



Astro lab literature analysis June 2001

Subject to Legal and Regulatory Review

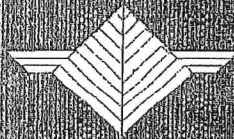




# Lessons Learned

- Child and Adolescent Market is large, PCP's playing increasingly important role - potential for growth is enormous.
- Without a Proactive Approach to Education and Public Relations We Run the Risk of Negative Press and Market Share Erosion.
- Safety is the predominant factor in assessing whether or not to prescribe an antipsychotic.
- FDA approved indication is necessary in order to maximize educational and initiate promotional opportunities.
- C&A market is becoming increasingly competitive.

Subject to Legal and Regulatory Review



# C&A SWOT ANALYSIS

## STRENGTHS

APS Market Leader in C & A Market  
Low Dose Availability/Oral Solution/Ease  
of Administration  
Trust/Experience with Drug  
Efficacy/Results  
Perceived AE Advantages Relative to Other APS  
Data (Relative to Other APS)  
KOL Support  
Cost Effectiveness  
Onset of Action

## OPPORTUNITIES

Poor Perception of Other APS For C & A Use  
External Data Sources (NIMH - RUPP  
Group)  
JNJ "Pediatric" Synergy (MCC, OMP, Alza)  
Under Served Market/Unsatisfied Market  
Better Diagnosis (DSM - V, Consensus Guidelines)  
Partnering Opportunities with Advocacy  
Microspheres/QS

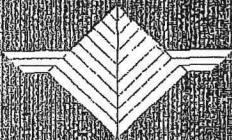
## WEAKNESSES

Safety Perceptions (EPS/TD, Prolactin,  
Weight Gain)  
Lack of Promotional  
Platform/Indication (Current Clinical  
Data Does Not Meet FDA Stated Needs)  
Lack of Support From Non-Psychiatry KOL's (Peds,  
Pharm., Ns, etc)  
Dose Range Ambiguity

## THREATS

PR - Damage to: RISPERDAL, Janssen, J & J  
Lack of Consensus - Diagnostic Specificity  
Other Therapeutic Classes (Mood Stabilizers,  
AED's, etc.)  
Lack of Global Alignment Regarding  
Indications/Filing Strategy  
Regulatory/Legal/Payers  
FDA Relabeling of Current RISPERDAL PI  
Geodon/Zyprexa/Seroquel Clinical Data

Subject to Legal and Regulatory Review

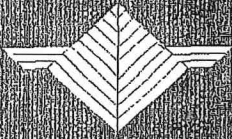


# Child and Adolescent Key Issues

- Underdeveloped market- limited education and awareness across diverse prescriber group.
- Psychopharmacology is a sensitive issue in children.
- Increasingly competitive market.
- Current development plan not optimal for US regulatory and market needs
- Lack of formal J&J pediatric franchise direction.

Subject to Legal and Regulatory Review





# Underdeveloped market - limited education and awareness across diverse prescriber group

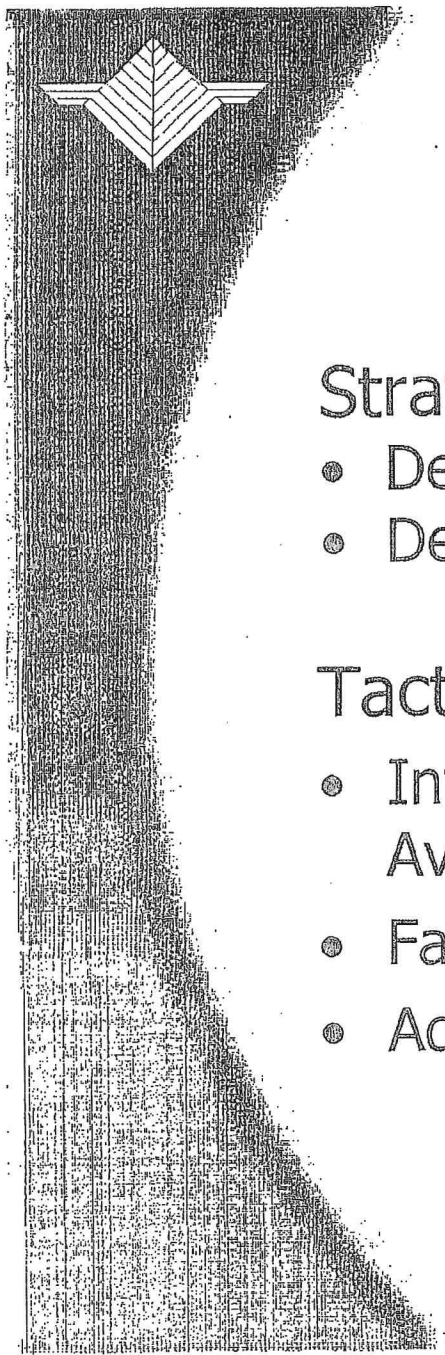
## Strategy:

- Expand Market by increasing awareness and appropriate use of RISPERDAL

## Tactics:

- Education Campaign Developing Consensus Guidelines on Appropriate Use of Psychotropics
- Education Campaign Ensuring Safe and Appropriate Use of RISPERDAL
- Symposium on diagnosis, Disease Severity, and Risk/Benefit Analysis of Available Treatment Options
- MSL development of KOL's
- Medical Services Presentation Slide Kit

Subject to Legal and Regulatory Review



# Psychopharmacology is a sensitive issue in children

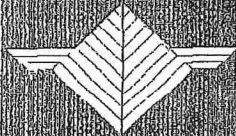
## Strategies:

- Develop C&A Media Management Plan
- Develop Public Relations Plan

## Tactics:

- Internal & External Spokespersons Trained and Available, Treatment Guidelines Disseminated
- Family Speaker's Forum
- Advocacy Spokespersons identified

Subject to Legal and Regulatory Review



# Increasingly Competitive Market Place

## Strategy:

- Differentiate Risperdal from other Antipsychotics and other Therapeutic Classes

## Tactics:

- Post Hoc Analysis, Chart Reviews, Targeted EMRP studies, Patient/caregiver survey analysis
- Develop Clinical Programs to Meet US Regulatory and Market Needs
- Discussion with FDA(CDMR, autism); Dose Finding for Other Therapeutic Areas, Agitation/Aggression

Subject to Legal and Regulatory Review



# Lack of Formal J&J Pediatric Franchise Direction in Pharma

## Strategy:

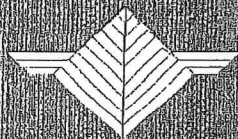
- J&J Pharm Sector Strategic Plan Development

## Tactics:

- Leverage Partnership Opportunities with McNeil Consumer Healthcare and Ortho McNeil Pharmaceuticals.

Subject to Legal and Regulatory Review

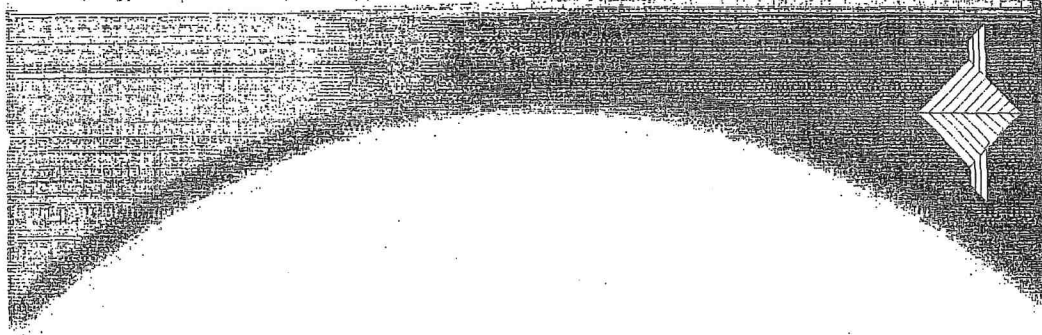




# Critical Success Factors

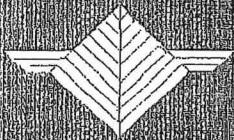
- Data Needed to Demonstrate:
  - Long Term Safety
  - Efficacy Across Diagnosis
  - Efficacy Across Symptoms
- Education Necessary With the Following Key Groups:
  - Clinicians
  - KOL's
  - Press
  - Advocacy Group Partnerships
- FDA Clarification

Subject to Legal and Regulatory Review



# Back Up

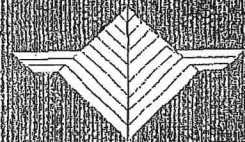
Subject to Legal and Regulatory Review



# Child & Adolescent Business Planning Team

- Carmen Deloria Marketing
- Magali Reyes-Harde Marketing
- Rob Lisicki Marketing
- Paul Mullen Market Research
- Joan Ramaize Information Management
- Ramy Mahmoud Medical Affairs
- Lauren Schubert Medical Affairs
- Ed Crumbley Medical Affairs
- Ann Clark Medical Services
- Emalie Burks Medical Services
- Pam Rasmussen Public Relations
- Evelyn Grasso-Sirface Reimbursement
- Bob Decker Finance
- Juan Jose Colon Finance
- Amy Grogg Outcomes Research

Subject to Legal and Regulatory Review



# Positioning Statement

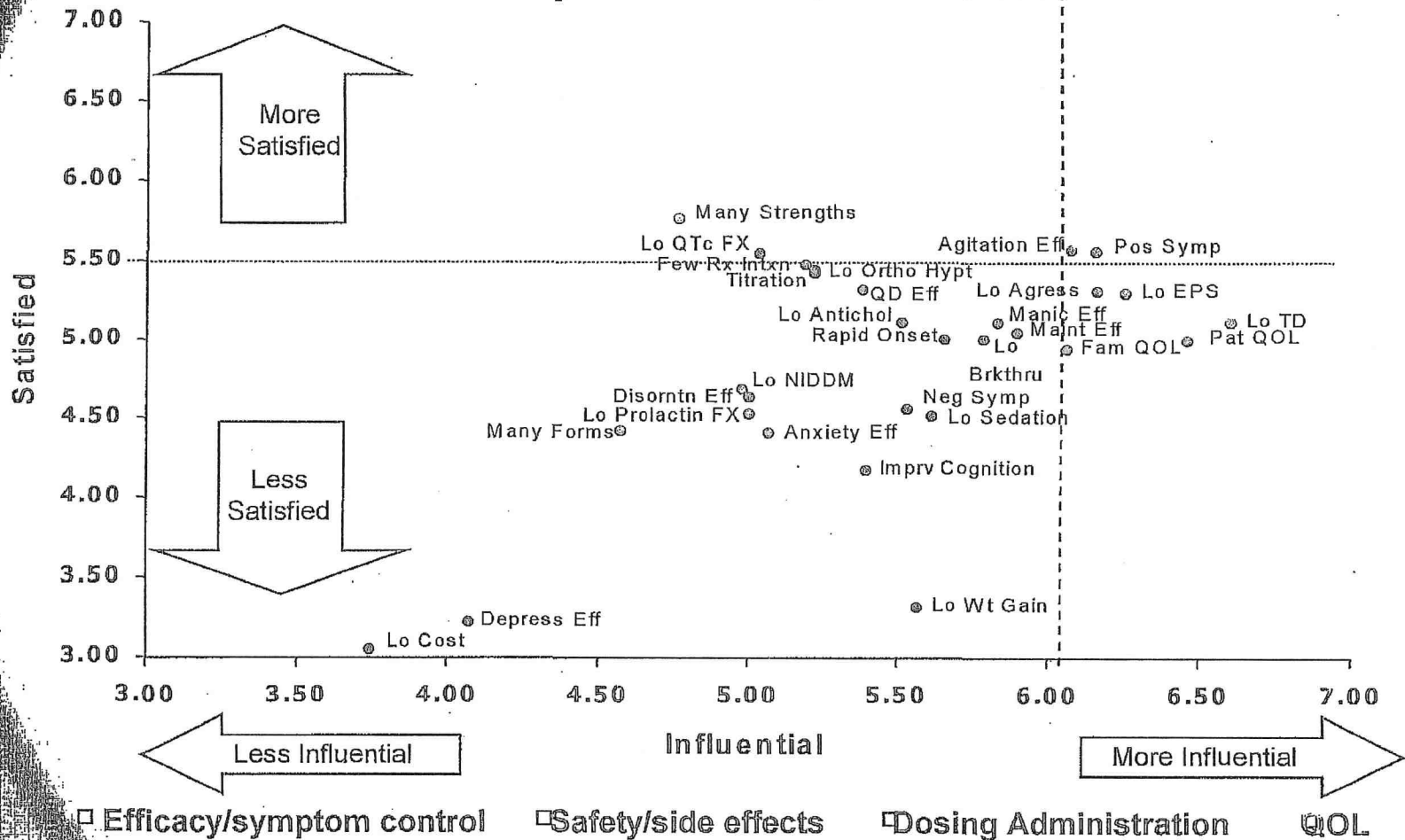
Broad spectrum RISPERDAL is 1st choice for psychotic & behavioral disorders because it is the only therapy to deliver rapid, sustained efficacy across the full range of symptoms and is uncompromised by safety concerns; benefiting patients, caregivers, healthcare professionals & payors

Subject to Legal and Regulatory Review



# PSYCHIATRIST SATISFACTION WITH ANTIPSYCHOTICS BY ATTRIBUTE IMPORTANCE\*

## - Child/Adolescent Disorders -



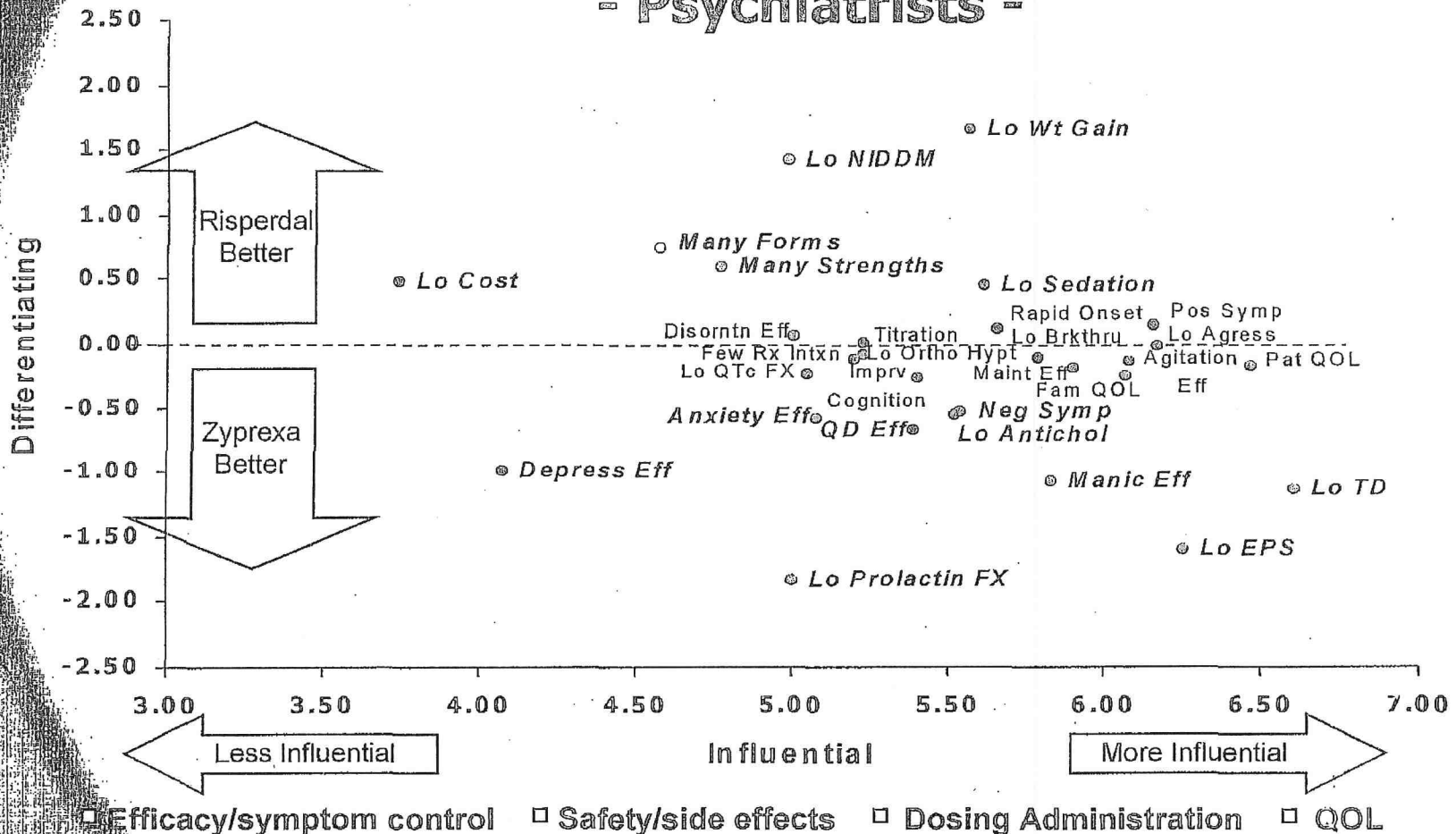
Since previous research has shown MD satisfaction with the ability of antipsychotics to address positive symptoms, the rating of this attribute was used to calibrate placement of the dotted horizontal

Subject to Legal and Regulatory Review

RISPERDAL Tracking Study - Use and Perceptions of Atypical Antipsychotics - April, 2001 - SMC (N=354; PCP, Psych)

# RISPERDAL v ZYPREXA FOR CHILD/ADOLESCENT DISORDERS\*

- Psychiatrists -

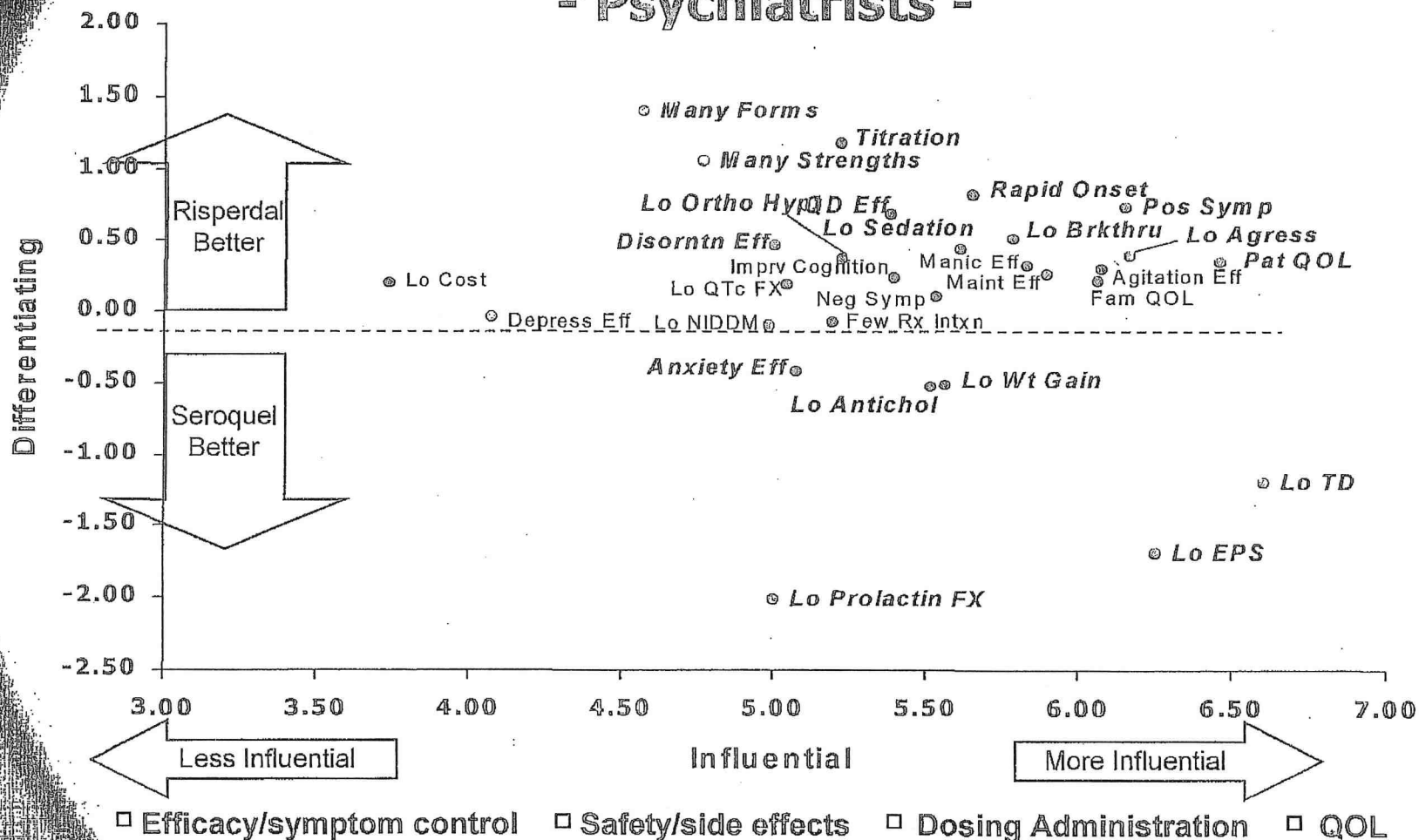


\* Attribute is bolded if significant difference between drugs  
Subject to Legal and Regulatory Review

RISPERDAL Tracking Study - Use and Perceptions of Atypical Antipsychotics - April, 2001 - SMC (N=354; PCP, Psych)

# RISPERDAL v SEROQUEL FOR CHILD/ADOLESCENT DISORDERS\*

## - Psychiatrists -



\* Attribute is bolded if significant difference between drugs  
 Subject to Legal and Regulatory Review

RISPERDAL Tracking Study -  
 Use and Perceptions of Atypical  
 Antipsychotics - April, 2001 -  
 SMC (N=354; PCP, Psych)



# Perceptions of Geodon

- A small number of psychiatrists have placed C & A patients on Geodon.
- Psychiatrists had no specific comments on the results of using Geodon – “too soon to tell”
- All were optimistic and hoped that claims of no weight gain would be substantiated in clinical practice
- Relevance of QTc risk to C & A patients remains unclear
  - Physicians tend to amplify their safety concerns when treating younger patients, but younger patients are the least likely to have cardiac risk factors which would contraindicate use of Geodon

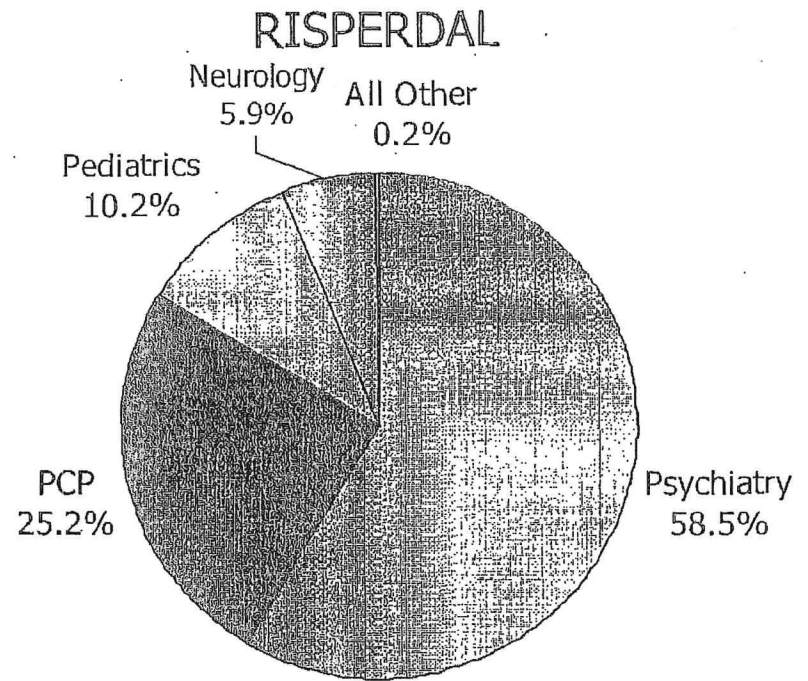
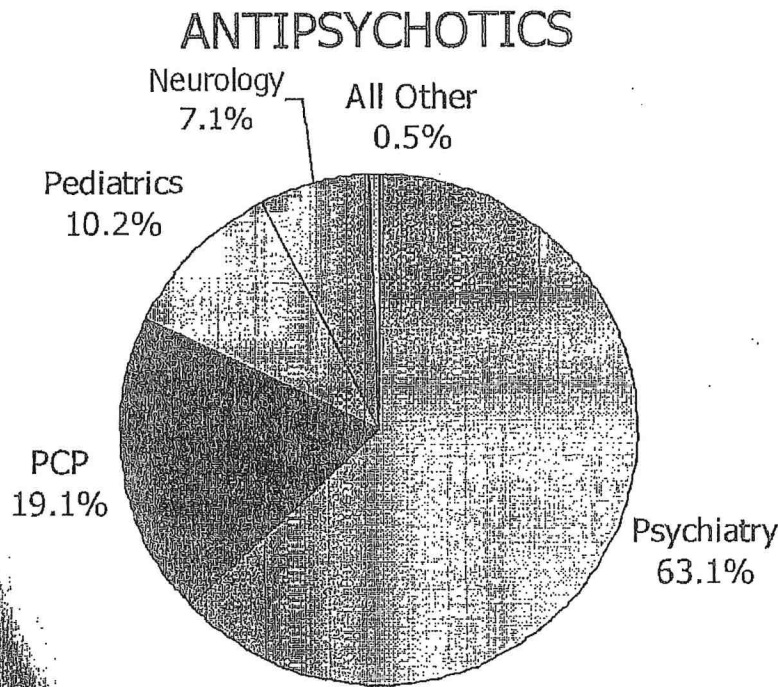
RISPERDAL Tracking Study - Use and Perceptions of Atypical Antipsychotics - April, 2001 - SMC (N=354; PCP, Psych)

Subject to Legal and Regulatory Review



# Antipsychotic Use by Specialty in Child and Adolescent Patients

Most of APS prescribing in child/adolescent patients is by psychiatrists, with primary care physicians and pediatricians also prescribing a significant amount.



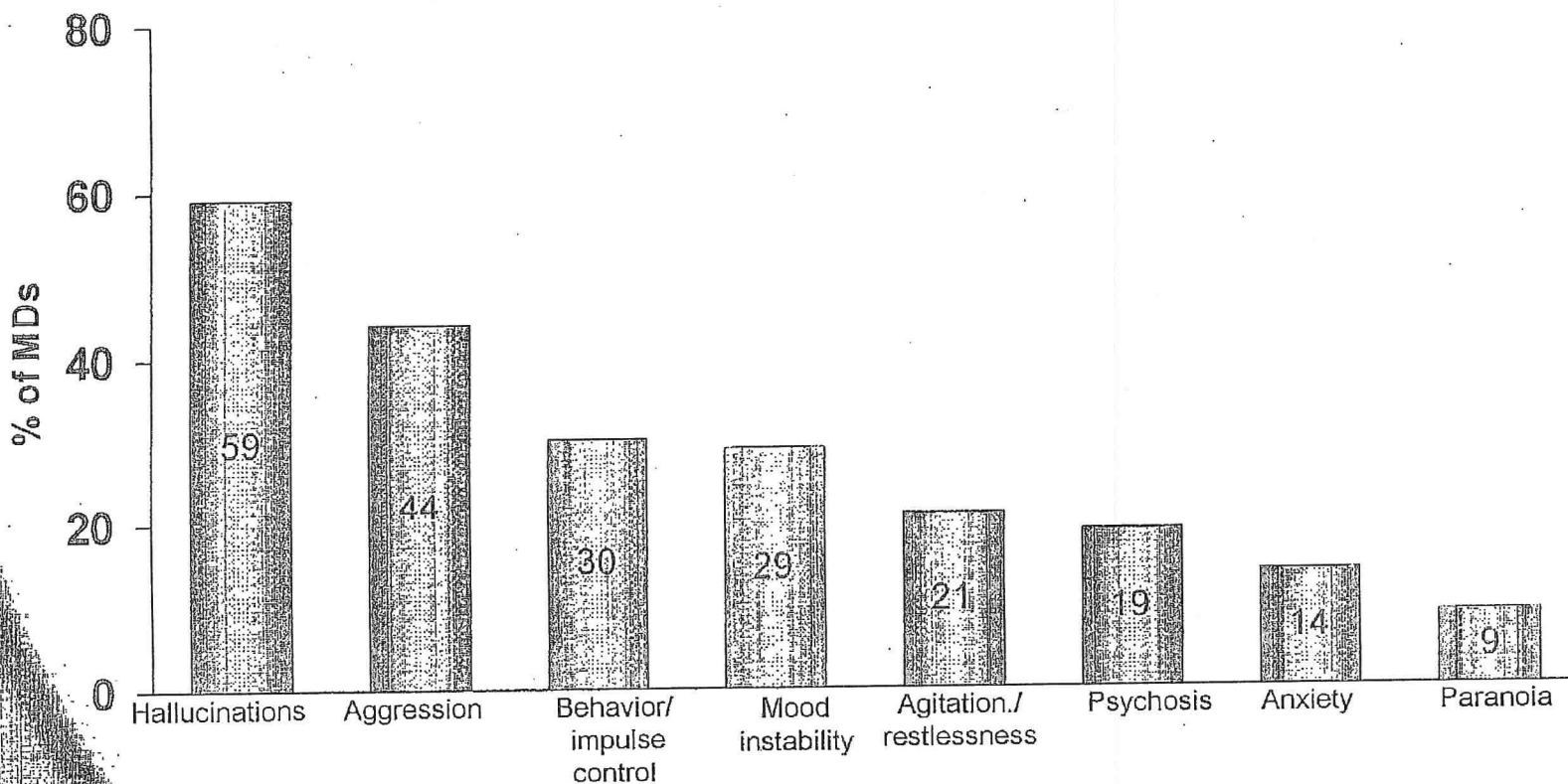
Child and adolescent defined as ages 0-19.

Source: IMS Health, NDTI, Full Year 2000

Subject to Legal and Regulatory Review

# CHILD & ADOLESCENT SYMPTOMS ADDRESSED WITH ANTIPSYCHOTICS\*

Hallucinations and Aggression are the top symptoms treated with antipsychotics in child and adolescent patients



Source: RISPERDAL Annual Tracking Study, May 201, n=354

Base: Q6, At least 20% patients on antipsychotics are under 20; n=75 (6 PCPs, 69 PSYCHs)

Subject to Legal and Regulatory Review

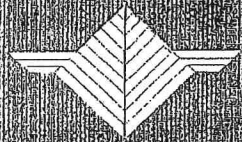


# Use of Antipsychotics

## *Average Percentage of Antipsychotic Prescriptions for C & A Patients Allocated to Each Age Group*

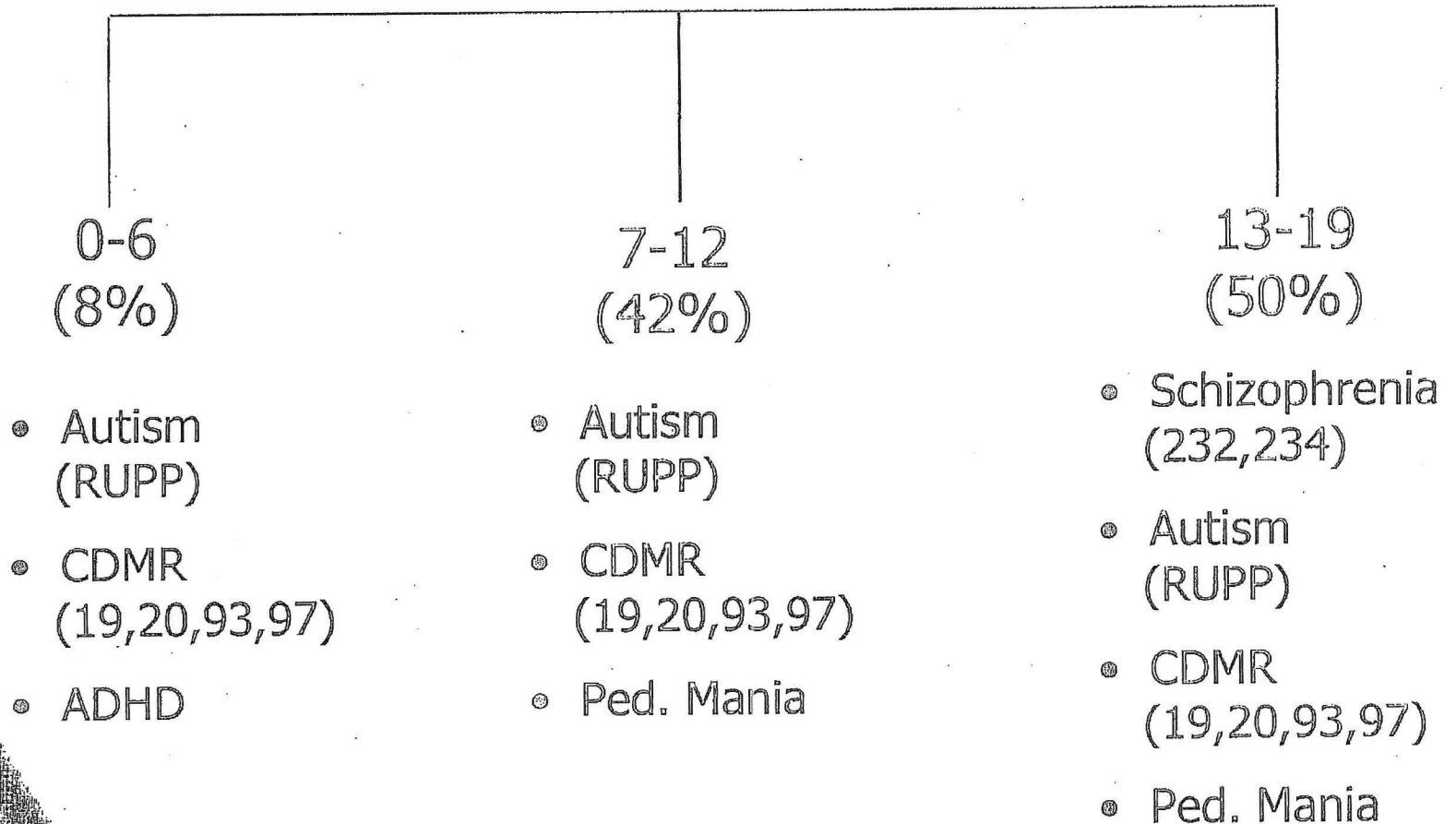
Specialty	0 to 6 Yrs	7 to 12 Yrs	13 to 18 Yrs
PCPs	1	24	76
PEDs	8	40	52
Total PSYCHs	6	32	64
GEN PSYCHs	5	26	69
CHILD PSYCHs	6	37	57
Total Physicians	5	33	63

RISPERDAL: Opportunity Analysis - Child and Adolescent Patients May 2001 n=101  
Subject to Legal and Regulatory Review



# Child & Adolescent Market Opportunities

JJRE 00575754  
Confidential/Produced in Litigation Pursuant to Protective Order



Subject to Legal and Regulatory Review





# Child & Adolescent Forecast

## JANSSEN PHARMACEUTICA PEDIATRIC SALES SUMMARY

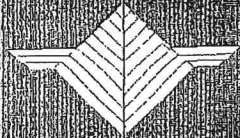
	2001	2002	2003	2004	2005	2006	2007	2008	2009
SCHIZO	51	56	55	54	55	56	57	42	24
BP	37	41	40	40	40	41	42	31	17
ADHD/CD	35	39	38	38	39	39	40	30	17
OTHERS	75	83	81	80	81	83	85	63	35
<b>TOTAL NO INDICATION:</b>	<b>\$ 198</b>	<b>\$ 219</b>	<b>\$ 215</b>	<b>\$ 213</b>	<b>\$ 215</b>	<b>\$ 220</b>	<b>\$ 225</b>	<b>\$ 166</b>	<b>\$ 92</b>

IF WE GET INDICATION FOR SCHIZO IN PEDIATRICS & LAUNCH IN 4Q03, WE WOULD ACHIEVE INCREMENTAL SALES:

SCHIZO	-	-	3	10	18	26	34	25	14
BP	-	-	2	6	11	16	22	16	9
ADHD/CD	-	-	7	29	51	75	99	73	41
OTHERS	-	-	2	7	12	17	23	17	9
<b>TOTAL</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 13</b>	<b>\$ 52</b>	<b>\$ 92</b>	<b>\$ 134</b>	<b>\$ 178</b>	<b>\$ 132</b>	<b>\$ 73</b>

<b>TOTAL SALES W/INDICATION:</b>	<b>\$ 198</b>	<b>\$ 219</b>	<b>\$ 228</b>	<b>\$ 264</b>	<b>\$ 307</b>	<b>\$ 354</b>	<b>\$ 403</b>	<b>\$ 298</b>	<b>\$ 165</b>
----------------------------------	---------------	---------------	---------------	---------------	---------------	---------------	---------------	---------------	---------------

Subject to Legal and Regulatory Review



# Clinical Data Key Messages

## 1. Safety

- A1. Low risk of EPS/TD
- A2. Low prolactin
- B. Low weight gain
- C. Low risk of diabetes
- D. Low sedation

## 2. Efficacy

- A. Efficacy across broad range of symptoms
- B. Efficacy for patients in multiple environments
- C1. 1st choice for adolescent schizophrenia
- C2. 1st choice for 1st break schizophrenia
- C3. Functionality/outcomes
- D. Low risk of relapse
- E. Improved compliance
- F. Rapid onset of action

## 3. Convenience/Dosing

- A. Improves functionality
- B. Low dose effectiveness
- C. Convenience/improves QoL for patients

## 4. Cost Effectiveness

- A. Most cost effective

Subject to Legal and Regulatory Review



# RISPERDAL C&A PME by Line Item

Description	2001 * PME(\$K)	Proposed 2002 PME(\$K)	2002 PME%
Medical Education	1,200	2,500	108%
Grants	75	150	100%
Advisory Boards	400	1,750	338%
Agency Fees	25	40	60%
Public Relations	50	500(Pam)	900%
Market Research	130	200	53%
Consultants	0	50	---
J&J Pediatric Sect.	0	50	---
Total	1,880	5,240	178%

\*estimated

Subject to Legal and Regulatory Review



# PME Breakdown

## Medical Education **\$2,500**

Teletopics	\$700
DLN	\$250
Audio Conferences	\$900
Consensus Guidelines	\$600

## Advisory Boards **\$1750**

Regional	\$750
MSL (KOL)	\$500
HOV	\$250
National	\$250

Subject to Legal and Regulatory Review



# PME Breakdown

## Public Relations **\$500**

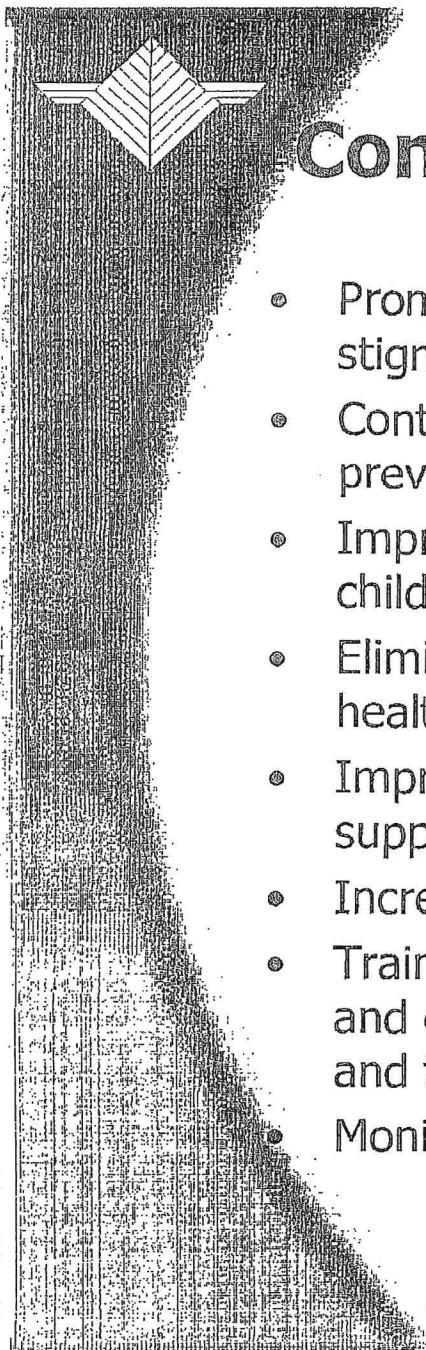
Response "Kit"	\$100
Advocacy Success Stories	\$50
Clinical "seeding"	\$50
International Consensus	\$300

## Market Research **\$200**

A&U	\$50
Educational Message	\$100
JNJ Pediatric	\$50

Subject to Legal and Regulatory Review

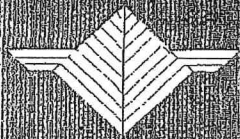




# Report of the Surgeon General's Conference on Children's Mental Health

- Promote Public Awareness of children's mental health issues and reduce stigma associated with mental illness.
- Continue to develop, disseminate, and implement scientifically proven prevention and treatment services in the field of children's mental health
- Improve the assessment and recognition of mental health needs in children.
- Eliminate racial/ethnic and socioeconomic disparities in access to mental healthcare
- Improve the infrastructure for children's mental health services including support for scientifically proven interventions across professions.
- Increase access to and coordination of quality mental health services
- Train frontline providers to recognize and manage mental health issues, and educate mental health providers in specifically-proven prevention and treatment services.
- Monitor the access to and coordination of quality mental health services.

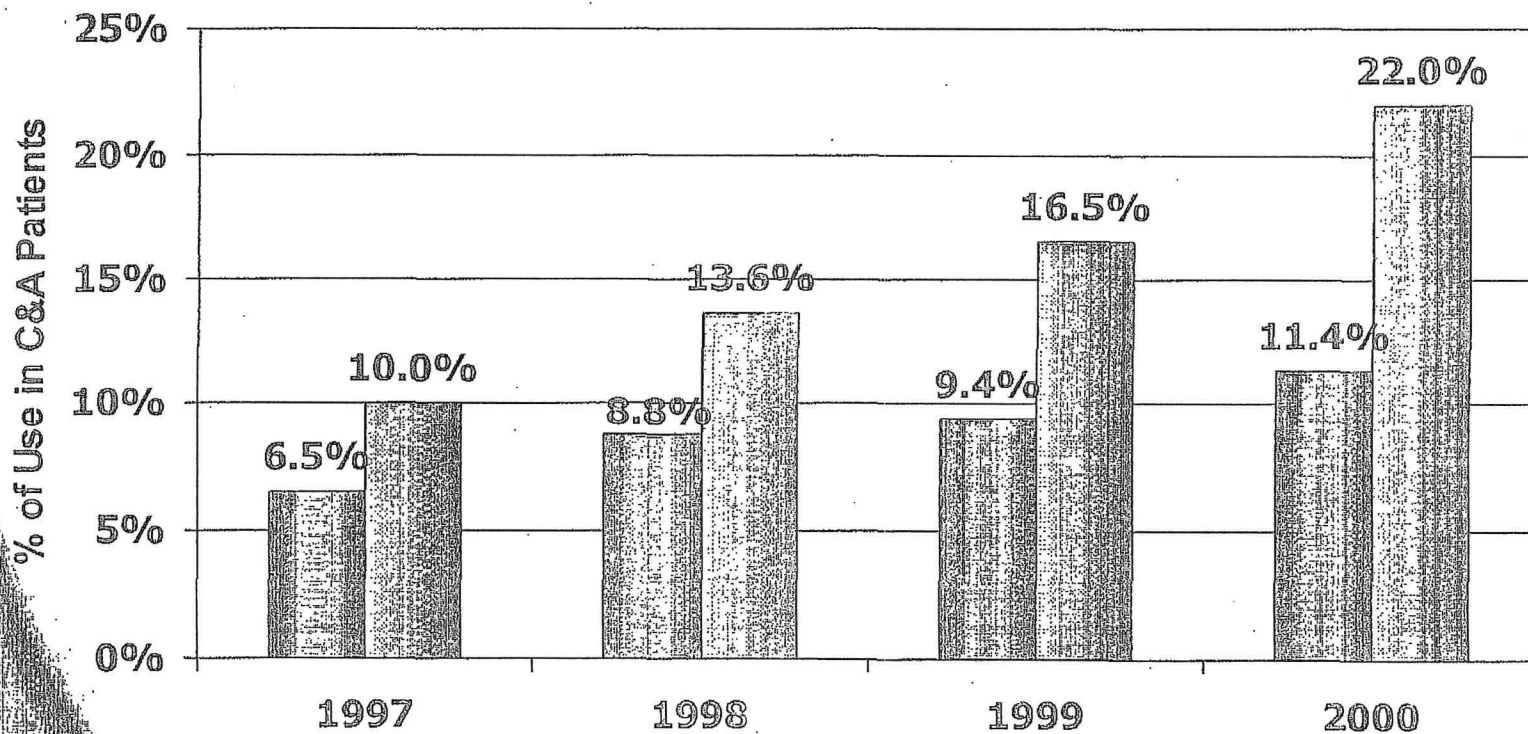
Subject to Legal and Regulatory Review



# Percent of Antipsychotic Drug Use in Child and Adolescent Market

The pediatric market is growing in importance to Risperdal and, to a lesser extent, the entire APS market.

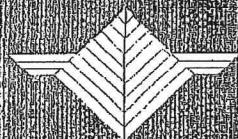
Antipsychotics Risperdal



Child and adolescent defined as ages 0-19.

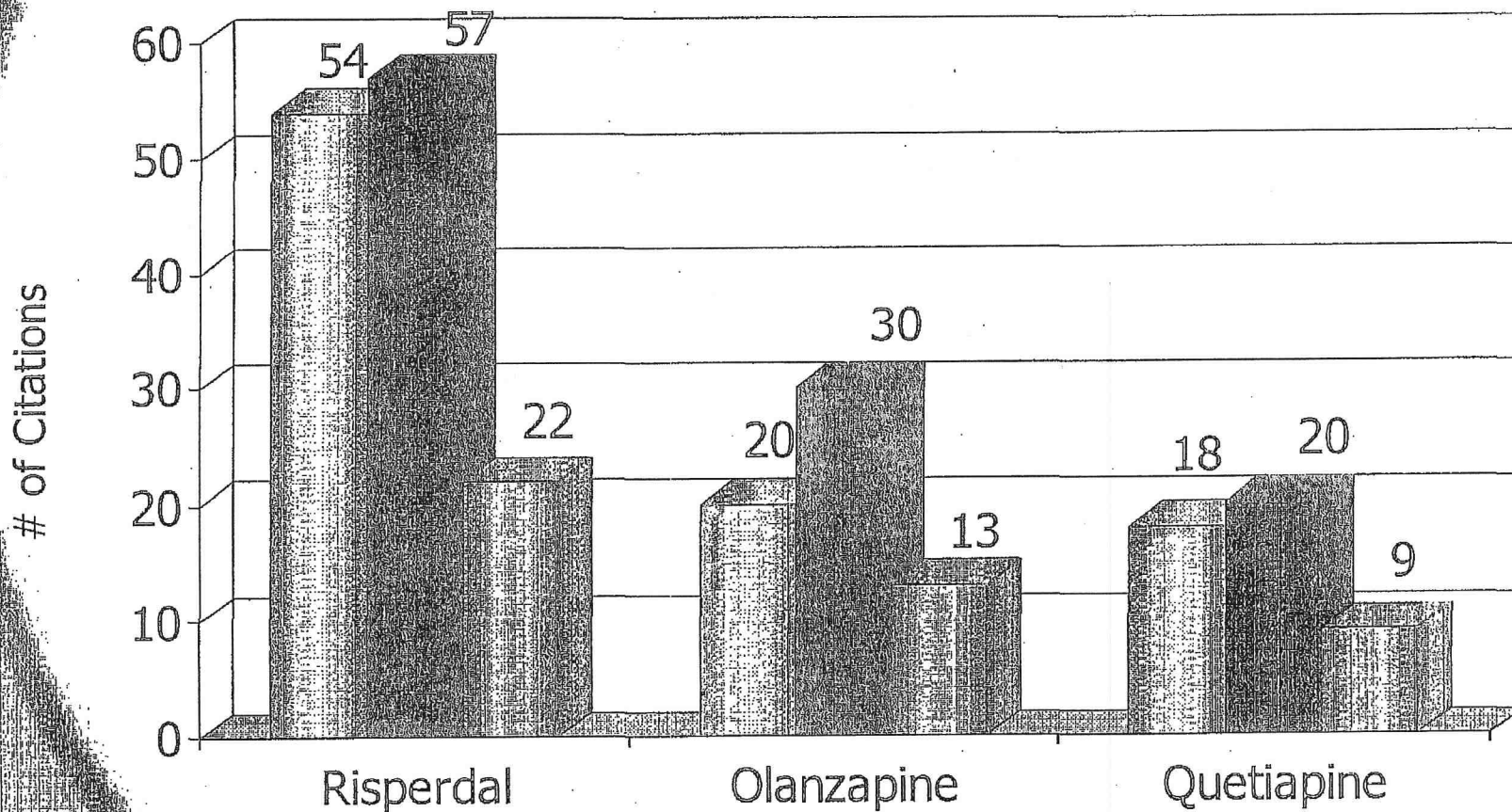
Source: IMS Health, NDTI

Subject to Legal and Regulatory Review



# Child & Adolescent Citations over time

■ 1999 ■ 2000 ■ 2001



Astro lab literature analysis June 2001  
Subject to Legal and Regulatory Review



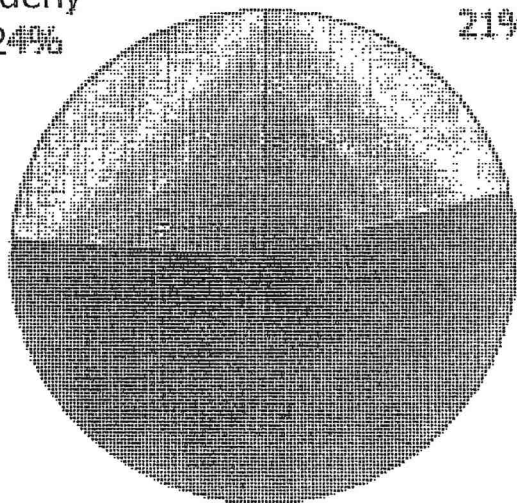
# RISPERDAL

## Distribution by Patient Age

Child and adolescent patients comprise 21% of Risperdal's overall uses and 12% of antipsychotic market uses.

### RISPERDAL

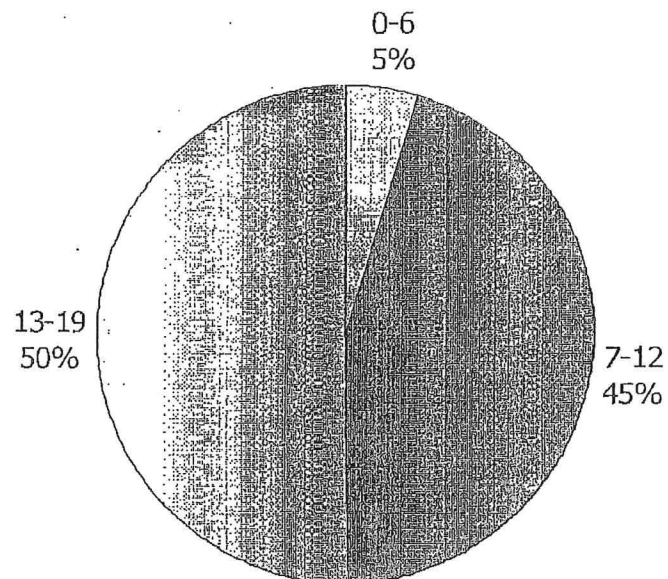
Elderly  
24%



Children  
21%

Adults  
55%

Half of Risperdal child and adolescent patients are over age 13.



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

Subject to Legal and Regulatory Review