

# Child and Adolescent & Other New Business

## 2003 Business Plan July 29, 2002

PLAINTIFF'S  
EXHIBIT  
19





# Child and Adolescent Business Planning Team

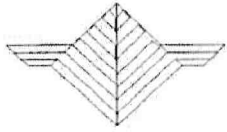
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- Tom Gibbs
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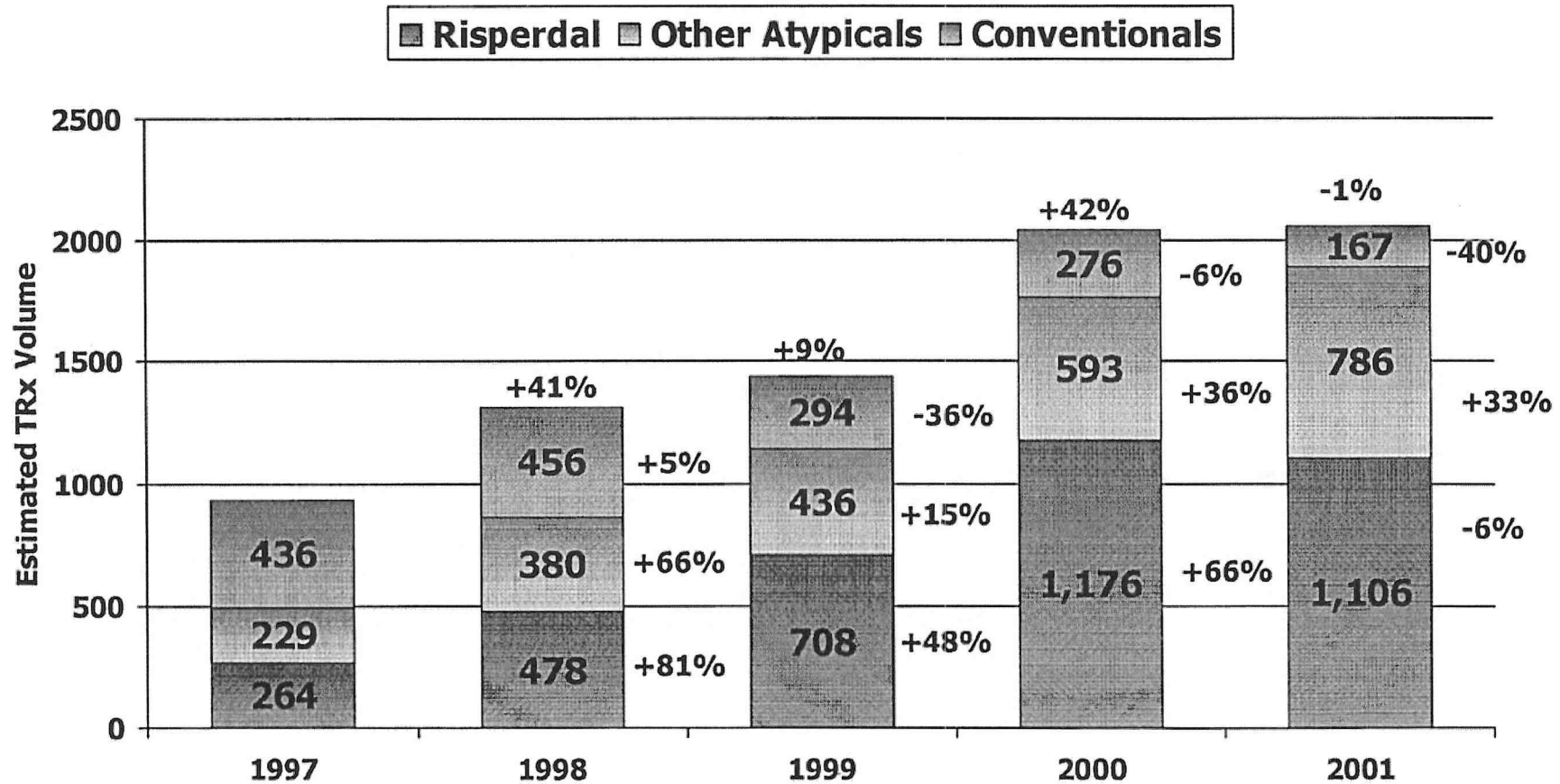
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# APS TRx Volume Growth Child and Adolescent Market

JJRE 02399408  
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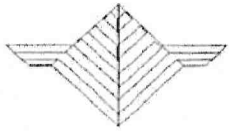


Source: IMS Health, NDTI and NPA Plus (Retail Only)

Child and adolescent defined as ages 0-17.

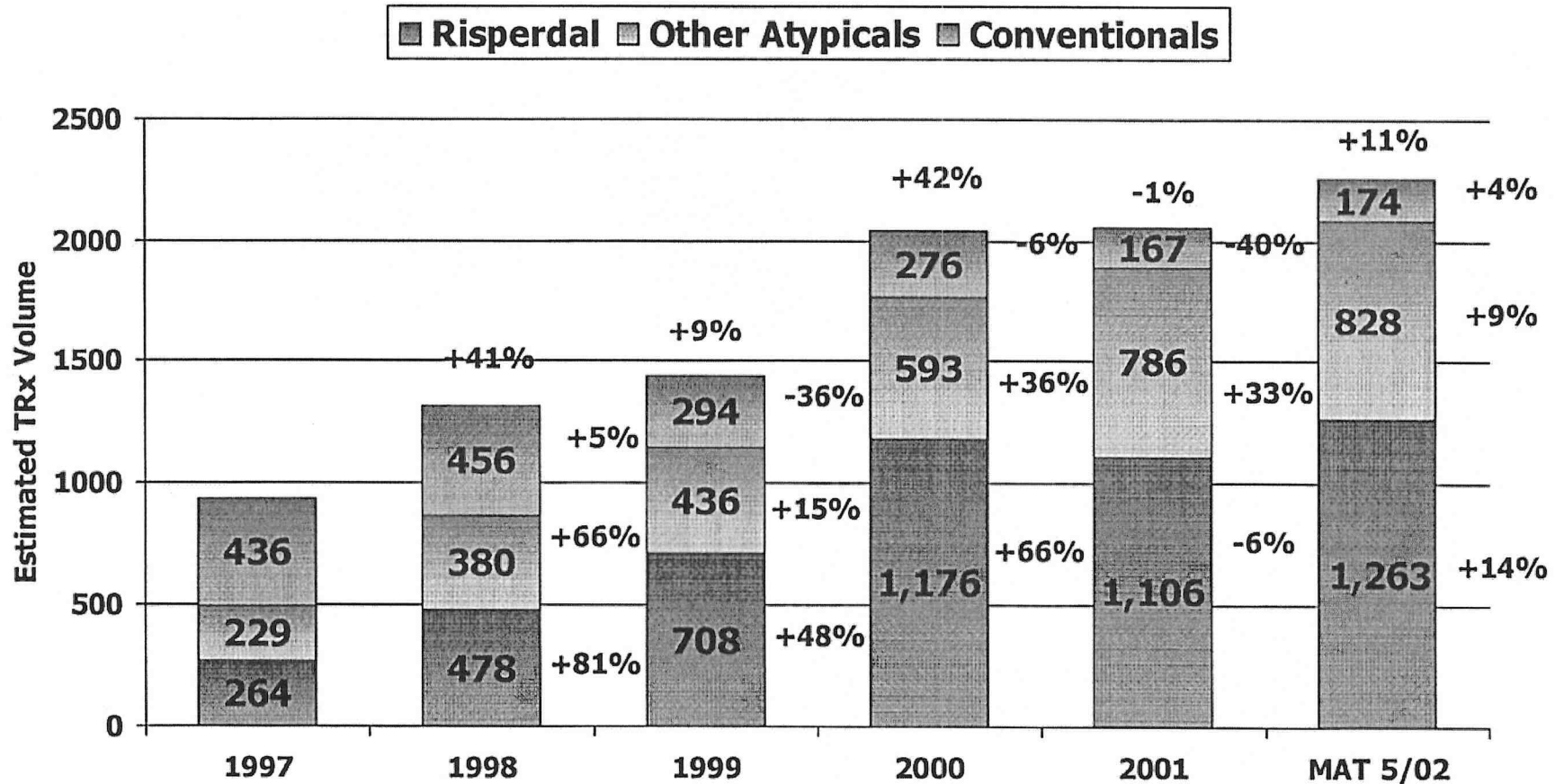
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# APS TRx Volume Growth Child and Adolescent Market

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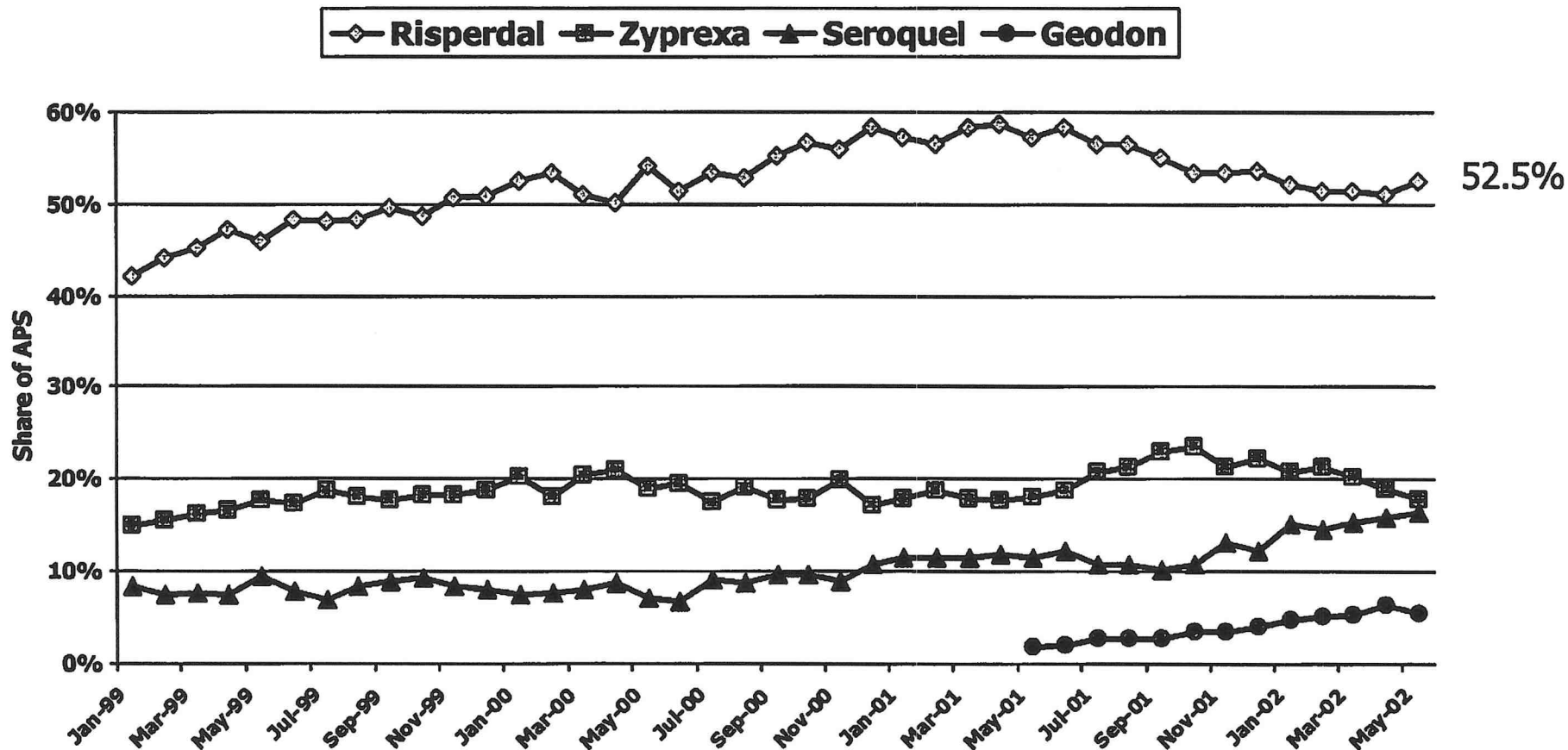
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# Antipsychotic Share in Child & Adolescent Market

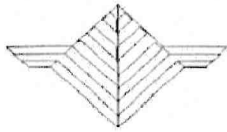
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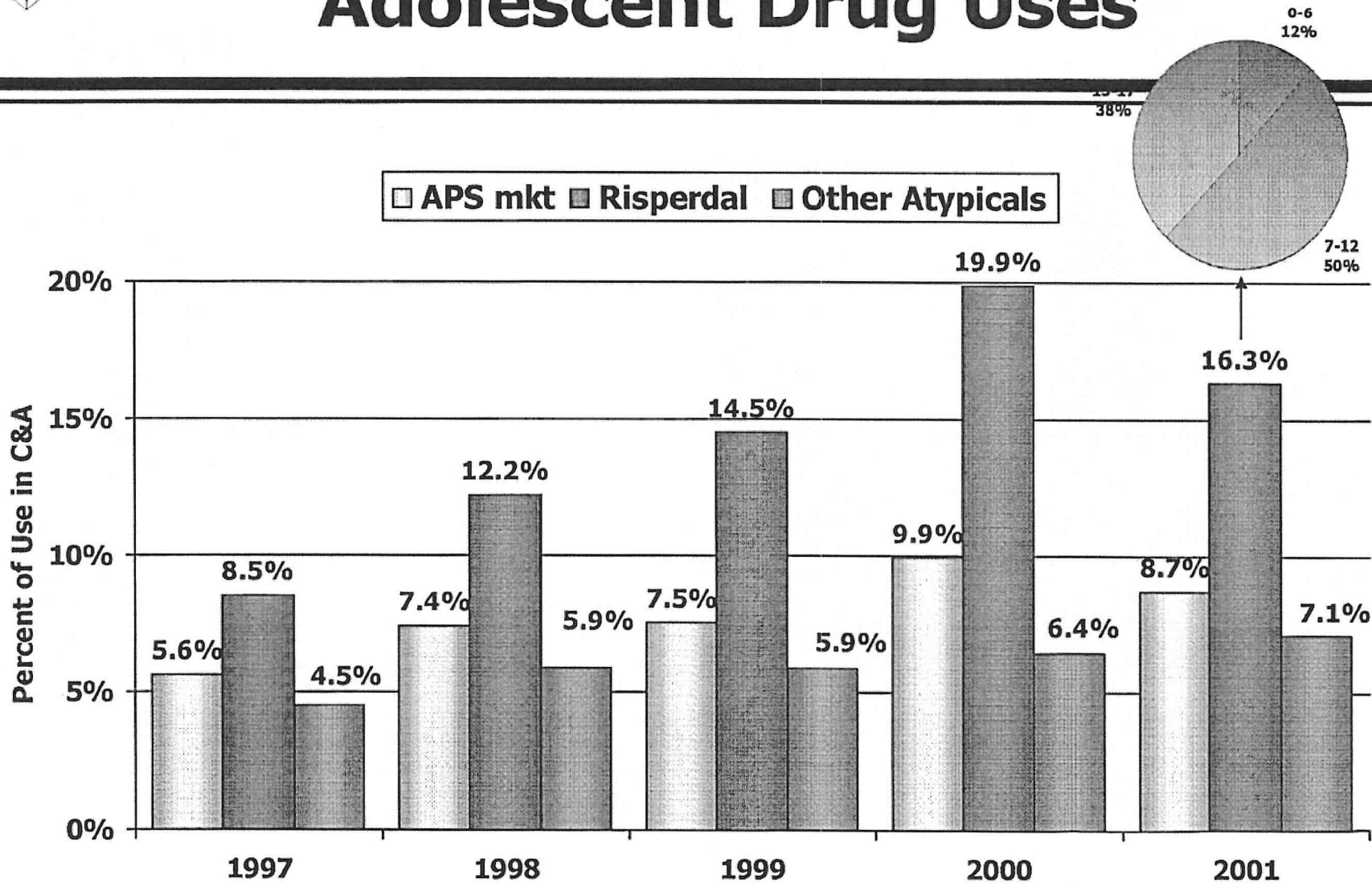
Subject to legal and regulatory review

Source: IMS Health, NDTI  
Child and adolescent defined as ages 0-17.

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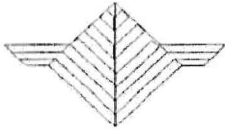
# Percent of APS Child & Adolescent Drug Uses



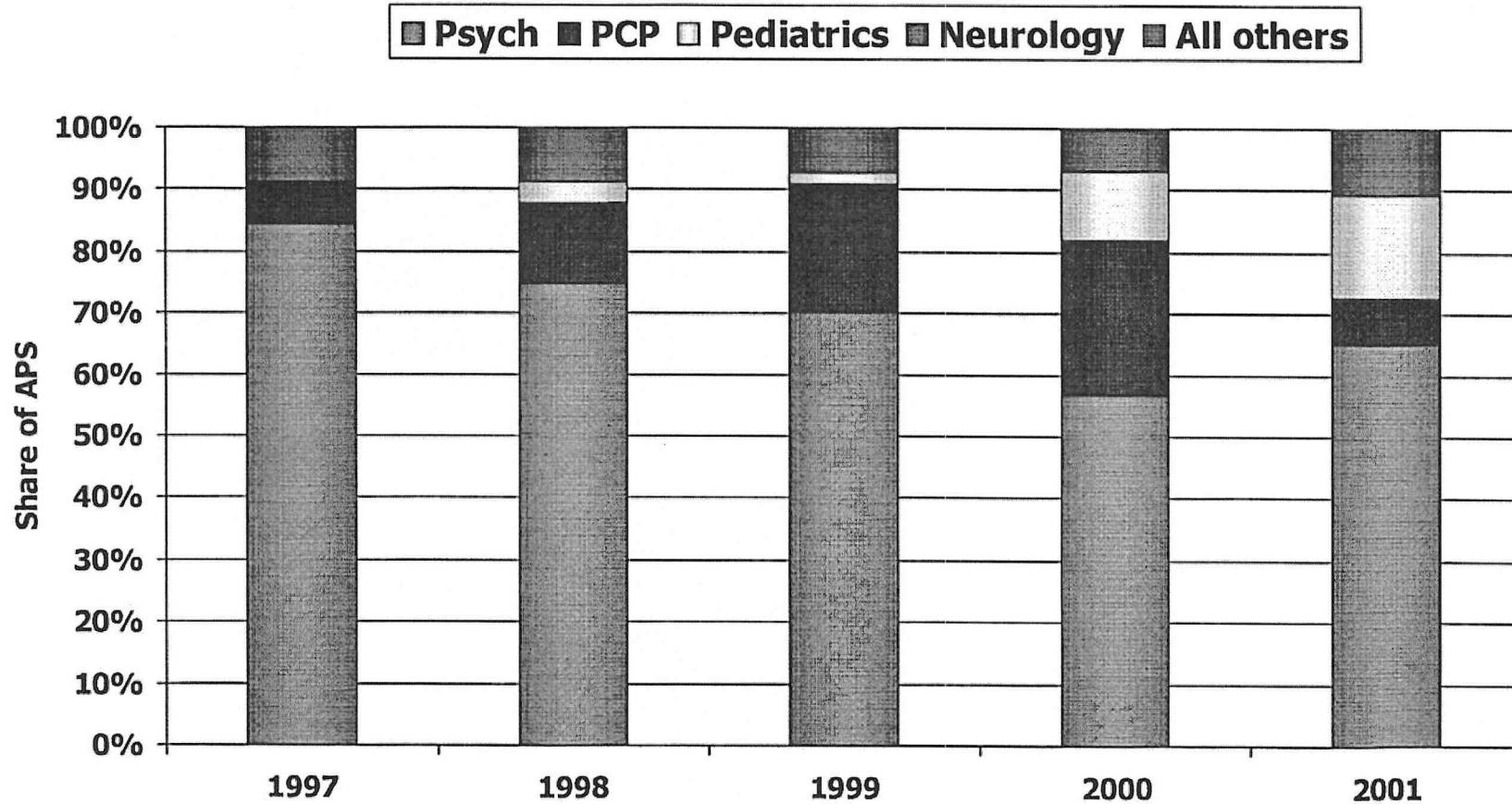
Subject to legal and regulatory review

Source: IMS Health, NDTI MAT ending 1Q02  
Child and adolescent defined as ages 0-17.

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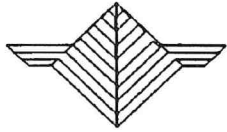
# Risperdal Child & Adolescent Trends by Specialty



Subject to legal and regulatory review

Source: IMS Health, NDTI MAT ending 1Q02  
Child and adolescent defined as ages 0-17.

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# Child and Adolescents: Opportunities and Requirements

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## Pediatric Exclusivity

- 6-month patent extension
- Awaiting written request from FDA
- Lilly has received request

## Pediatric Rule

- Bipolar trials will be required
- Informed FDA that we will not act until exclusivity requirements are elucidated

## Schizo- phrenia

- Pivotal trial is ongoing
- Will likely be part of exclusivity requirements
- Indication projected 2005+

## Autism

- Awaiting NIMH RUPP trial database
- JJPRD/JPI will evaluate options for registration



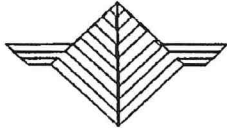
# Key Publication Dates

<b>Study</b>	<b>Disease</b>	<b>Journal</b>	<b>Date</b>
RUPP	Autism	NEJM	Aug. 2002
RIS USA 98	CDMR ST	Am J Psych	Aug. 2002
RIS CAN 19	CDMR ST	JAACAP	Sept. 2002
RIS CAN 20	CDMR LT	Pediatrics	Oct. 2002
RIS USA 97	CDMR LT	Am J Psych	3Q2002 Sub.
RIS INT 41	CDMR LT	TBD	4Q2002 Sub.

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ST=Short Term  
LT= Long Term

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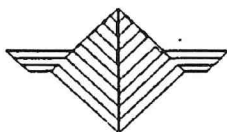
# Lessons Learned

## *Lessons Learned*

- C&A market is becoming increasingly competitive: increased comfort with newer agents
- Prolactin, EPS, TD and weight gain continue to be important issues (especially long-term implications)
- Competitors are driving negative safety and tolerability perceptions for Risperdal (e.g., prolactin)
- C&A market growth has flattened
- Advocacy is seeking to define a public position regarding C&A use of antipsychotics

## *Implications*

- Generation and dissemination of current and future data is essential
- Dissemination of re-analyses of safety databases is critical
- Stigma and lack of education regarding appropriate use of APS in C&A must be addressed
- Opportunities exist for partnerships with advocacy



# SWOT Analysis

## STRENGTHS

- **APS market leader in C & A market**
- **Perceived efficacy advantage:**
  - **trust and experience with product**
- **Most data (Relative to Other APS)**
- **Low dose availability/oral Solution**
- **KOL support**
- **Early onset of action**

## WEAKNESSES

- **Safety perceptions (Prolactin, EPS, TD, Weight Gain)**
- **Lack of awareness of appropriate dosing**
- **Lack of promotional platform/indication**
- **Lack of sedation relative to other APS**

## OPPORTUNITIES

- **External data sources (e.g., RUPP)**
- **Clinical partnerships (e.g., Mass General)**
- **Under serviced market/unsatisfied market**
- **Zyprexa safety profile (e.g., metabolic)**
- **JNJ "pediatric" synergy (MCC, OMP, Alza)**
- **Better diagnosis (DSM - V, consensus guidelines)**
- **Advocacy is seeking partnership**
- **Quicksolv**

## THREATS

- **Further delay of labeling/exclusivity**
- **Negative PR regarding use of APS in C&A**
- **Increased focus of competition on C&A market**
- **Perceived legal liability by prescribers**
- **Sensitivity regarding use of APS in C&A**
- **Emerging clinical data with other APS**
- **Migration to other classes of drugs**

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# Key Issues

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- Use of psychotropic medications in child and adolescents remains controversial
- Limited education and awareness of appropriate use of APS
- Physician misperception of Risperdal safety profile: driven primarily by increasingly competitive market
- Lack of indication



# Key Issues and Strategies

***Use of psychotropic medications in C&A remains controversial***

***Limited education and awareness of appropriate use of APSs***

***Physician misperception of RIS safety profile: driven primarily by increasingly competitive market***

***Lack of indication***

## ***Core Strategies***

- Raise awareness regarding prevalence, economic and emotional burden of untreated C&A mental illness
- Develop educational platform to establish the role of APSs in the treatment of C&A mental illness
- Establish Risperdal as having a favorable risk-benefit ratio relative to other compounds
- Partner with JJPRD and Pediatric Drug Development to facilitate development plans

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# Strategic Initiatives

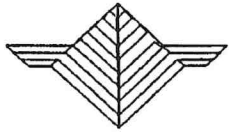
*Use of psychotropic medications in C&A remains controversial*

*Limited education and awareness of appropriate use of APSs*

*Physician misperception of RIS safety profile*

*Lack of indication*

<i>Raise awareness regarding prevalence, economic and emotional burden</i>	<i>Develop educational platform</i>	<i>Establish Risperdal as having a favorable risk-benefit ratio</i>	<i>Partner with JJPRD to facilitate development plans</i>
<ul style="list-style-type: none"> <li>• Partner with advocacy to drive caregiver education</li> <li>• Generate and disseminate data supporting clinical rationale and utility of APS in C&amp;A</li> <li>• Leverage CAPRI initiative with NIMH</li> <li>• Leverage J&amp;J-MGH Pediatric Psychopathology Center to drive awareness</li> </ul>	<ul style="list-style-type: none"> <li>• Partner with McNeil to drive and leverage educational program</li> <li>• Targeted medical education to pediatricians and neurologists</li> <li>• Leverage J&amp;J-MGH Pediatric Psychopathology Center to drive educational needs</li> </ul>	<ul style="list-style-type: none"> <li>• Neutralize safety and tolerability concerns</li> <li>• Leverage current datasets</li> <li>• Develop EMRP plan addressing datagaps: ADHD, bipolar disorder, autism, acute agitation, Tourette's</li> <li>• Maximize RUPP autism publication</li> </ul>	<ul style="list-style-type: none"> <li>• Work to expedite enrollment in ongoing Schizophrenia trial</li> <li>• Assist in development of adolescent bipolar trial</li> <li>• Expedite transfer and analysis of RUPP database</li> <li>• Work with JJPRD and Pediatric Development Group to expedite receipt of written request</li> </ul>



# Use of psychotropic medications in children is controversial

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- Raise awareness regarding prevalence, economic, and emotional burden of untreated C&A mental illnesses and the long-term implications

## **Key Tactic: C&A Mental Health Summit**

### Description

One day national summit which addresses current issues in mental illnesses in children and adolescents

### Audience

Advocacy, KOLs, AACAP, NIMH



# Limited education and awareness of appropriate use of APS

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- Develop educational platform to establish the role of APSs in the treatment of C&A mental illness

## **Key Tactic#1: "Branded" educational initiative**

### Description

Multi-medium, comprehensive branded educational campaign on the role of APS in the treatment of C&A mental health: Centers of excellence, Regional CME symposia, monographs

### Audience

National and regional key opinion leaders, community based physicians

## **Key Tactic#2: Academic collaboration (MGH and CAPRI)**



# Physician misperception of Risperdal safety profile

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- Establish Risperdal as having a favorable risk-benefit ratio relative to other compounds
  - Leveraging current datasets
  - Generating new data to address identified gaps

**Key Tactics #1: Re-analysis and dissemination of CDMR database addressing: prolactin, EPS/TD, weight gain, development, PK**

**Key Tactic #2: Conduct selected EMRP studies targeting:**

- Treatment-refractory ADHD
- Bipolar disorder
- Acute agitation
- Autism
- Tourette's

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# Lack of indication

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- Partner with JJPRD and J&J Pediatric Institute to facilitate current development plans
  - RUPP (autism)
  - Schizophrenia
  - Bipolar Disorder
  - Exclusivity

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INSERT MEDICAL AFFAIRS SLIDE

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# Market Research Plan

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<i><b>Program</b></i>	<i><b>Objectives</b></i>	<i><b>Timing/Cost</b></i>
C&A Landscape Study	Determine diagnostic and treatment trends in C&A mental health market by specialty	1Q03/\$150k
TBD based on identified needs and final clinical development plans	TBD	TBD

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# Risperdal C&A 2003 PME's

JJRE 02399426  
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<i>Description</i>	<i>2002 PME (\$K)</i>	<i>Proposed 2003 PME (\$K)</i>	<i>2003 PME (%)</i>
<b>Medical Marketing/Education</b>	<b>3,890</b>	<b>3,300</b>	<b>51.6%</b>
CME Branded Initiative		1,800	
PsychLink/Teletopics		450	
Symposia (2)		350	
Publications		500	
National Ad Board		200	
<b>Advisory Boards (RAB/HOV)</b>	<b>1,800</b>	<b>1,900</b>	<b>29.7%</b>
<b>Public Relations</b>	<b>325</b>	<b>500</b>	<b>7.8%</b>
C&A Summit		400	
Other		100	
<b>Grants</b>	<b>160</b>	<b>300</b>	<b>4.6%</b>
<b>Other</b>	<b>225</b>	<b>400</b>	<b>6.3%</b>
<b>Total PME</b>	<b>\$6,400</b>	<b>\$6,400</b>	<b>100%</b>

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# Critical Success Factors

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- Maximize existing clinical data including dissemination and re-analyses
- Generate new data in key diagnostic/symptom areas
- Neutralize misconceptions about Risperdal's safety profile
- Gaining acceptance of the usage of APS in C&A
- Build new and strengthen existing internal and external partnerships
- Finalize clinical development plan (i.e., exclusivity, labeling)



# "Quicksolv" Opportunity

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- Opportunity for expanded product differentiation
  - Convenience (unit dose, no mixing, no water, etc.)
  - Difficulty swallowing
  - Compliance (cheeking)
- Segmentation
  - Special patient populations
    - Geriatrics
    - Pediatrics (upon approval)
  - Treatment settings
    - Acute care/Institutions
    - Long-term care



# Critical Ongoing/Next Steps

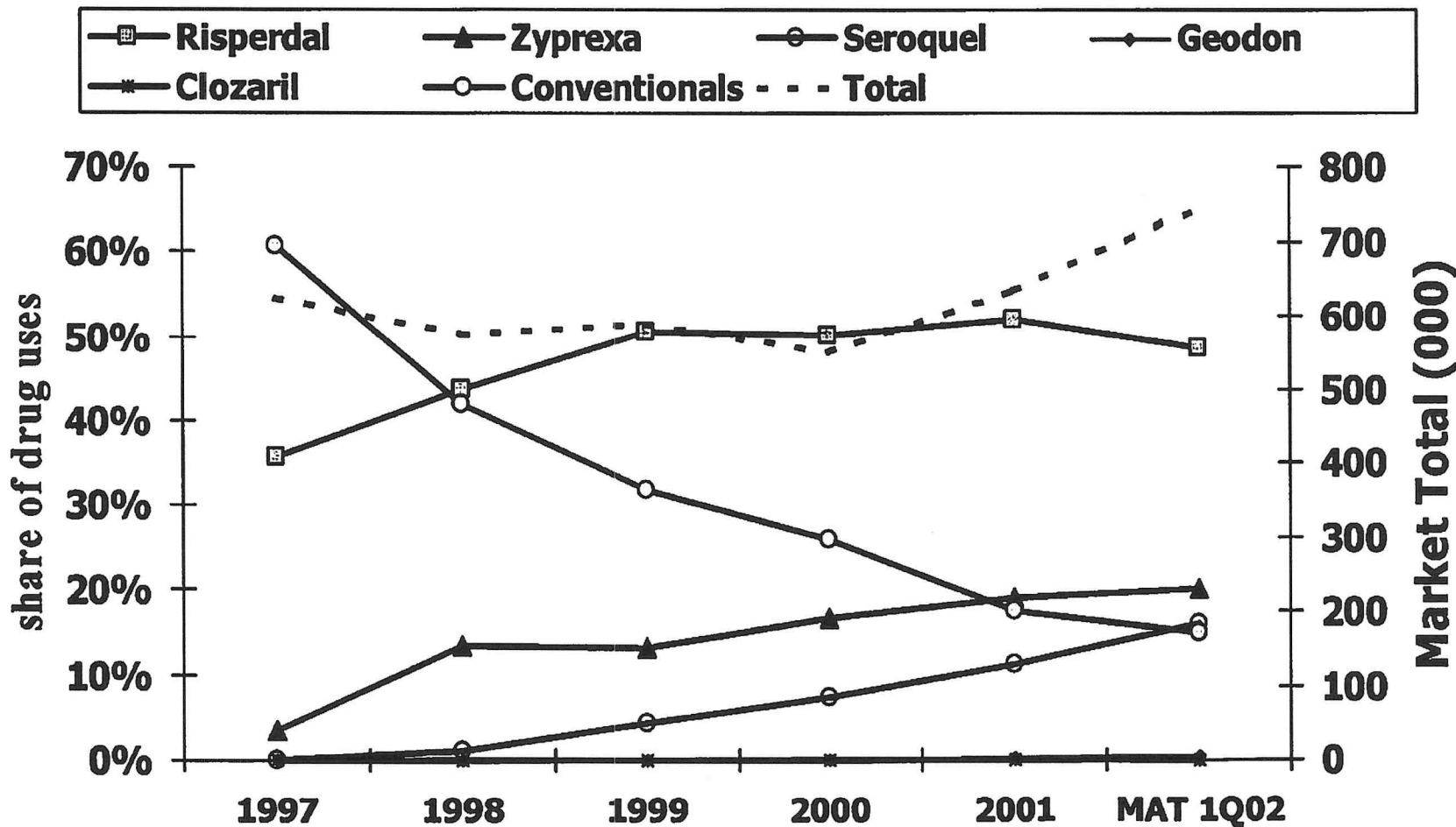
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- Market research
  - Back-up tradename generation/testing: completed
  - Pricing research: ongoing
  - Message/flashcard testing: ongoing
- Development of promotional platform
  - Integration in acute care and long term care strategies
  - Complimentary positioning with oral solution
- Medical Affairs clinical plan
  - EMRP
  - Incorporation in acute care study vs. Zyprexa IM



# Antipsychotic Market Dementia Share Trends



Subject to legal and regulatory review

Source: IMS Health, NDTI

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# Dementia - BPSD

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- sNDA file planned for mid-2003; anticipated launch 1Q05
- Zyprexa anticipated launch date tracking with Risperdal
- Management of "CVA issue" ongoing
- 2003 efforts will focus on medical marketing programs



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# Back-Up

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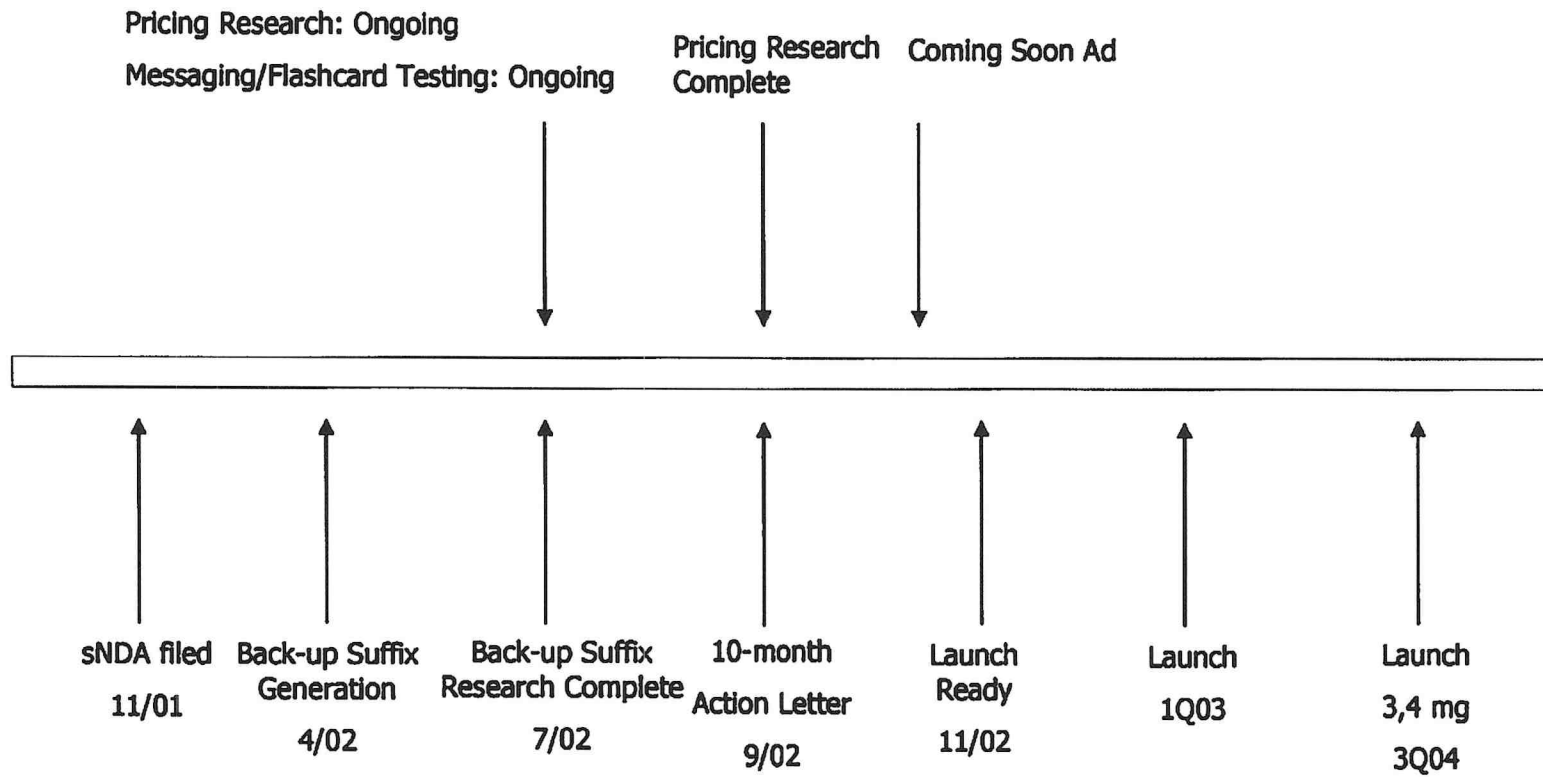
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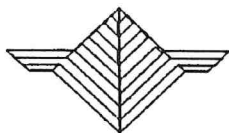
# Quicksolv Timeline of Key Activities

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# Risperdal LTC Share Change by LTC Pharmacy Provider

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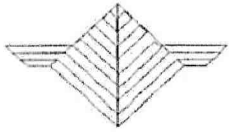
2001 LTC account trends mirror NPA LTC share loss

<b><u>Provider</u></b>	<b><u>4Q00</u></b>	<b><u>4Q01</u></b>	<b><u>Change</u></b>
IMS NPA LTC	36.8%	34.7%	-2.1
Omnicare	57.0%	54.7%	-2.3
PharMerica	52.2%	50.6%	-1.6
NCS	55.1%	50.6%	-4.5
NeighborCare	53.6%	49.9%	-3.6
APS	55.8%	51.6%	-4.1
SunScript	45.6%	45.9%	+0.4

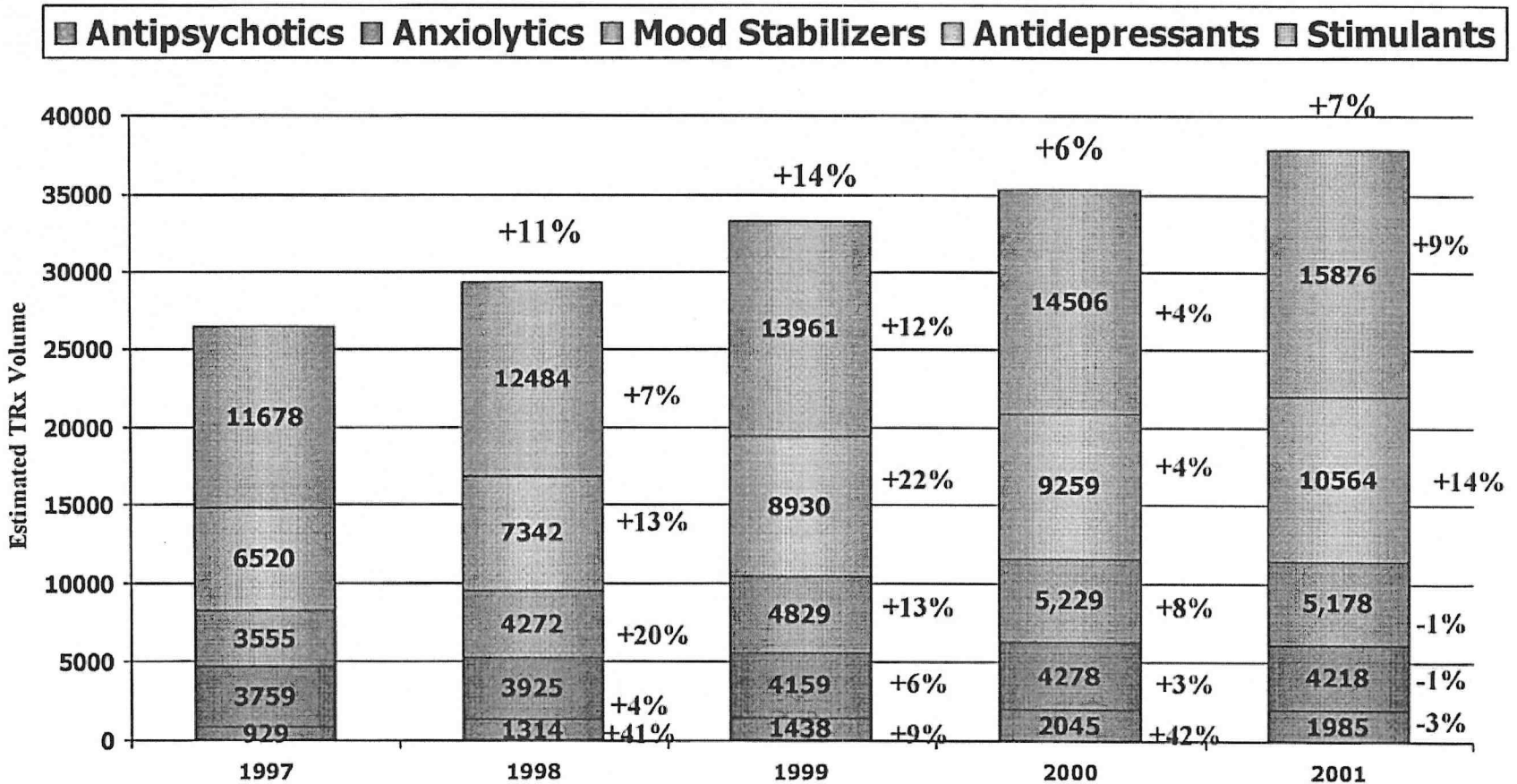
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Source: IMS Health; JJHCS Internal Database

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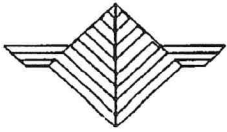


# CNS TRx Volume Growth Child and Adolescent Market

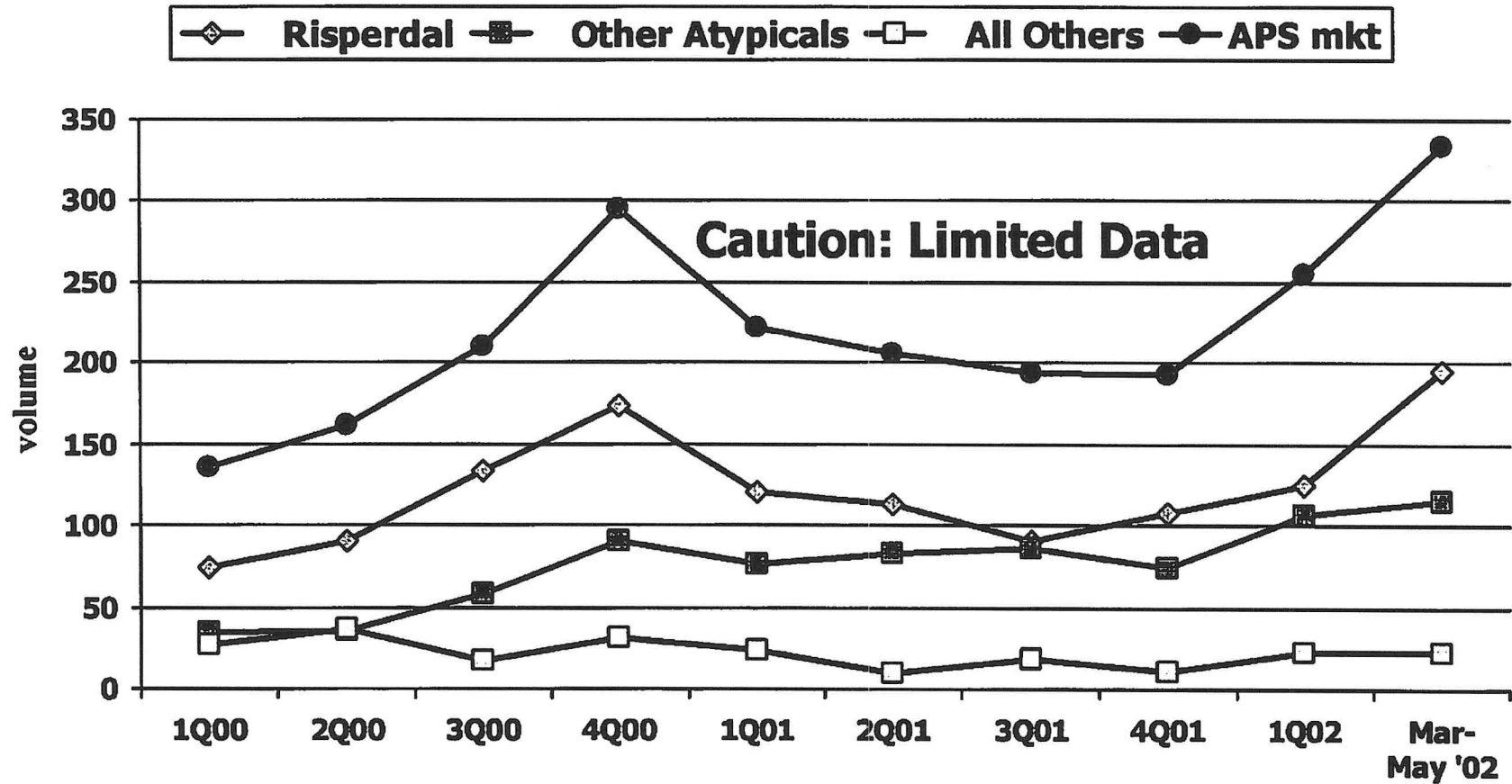


Source: IMS Health, NDTI and NPA Plus (Retail Only)  
Child and adolescent defined as ages 0-17.

Subject to legal and regulatory review



# Antipsychotic Volume in C&A Market By Quarter

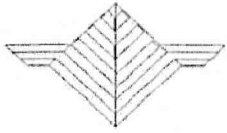


Source: IMS Health, Quarterly NDTI data

Child and adolescent defined as ages 0-17.

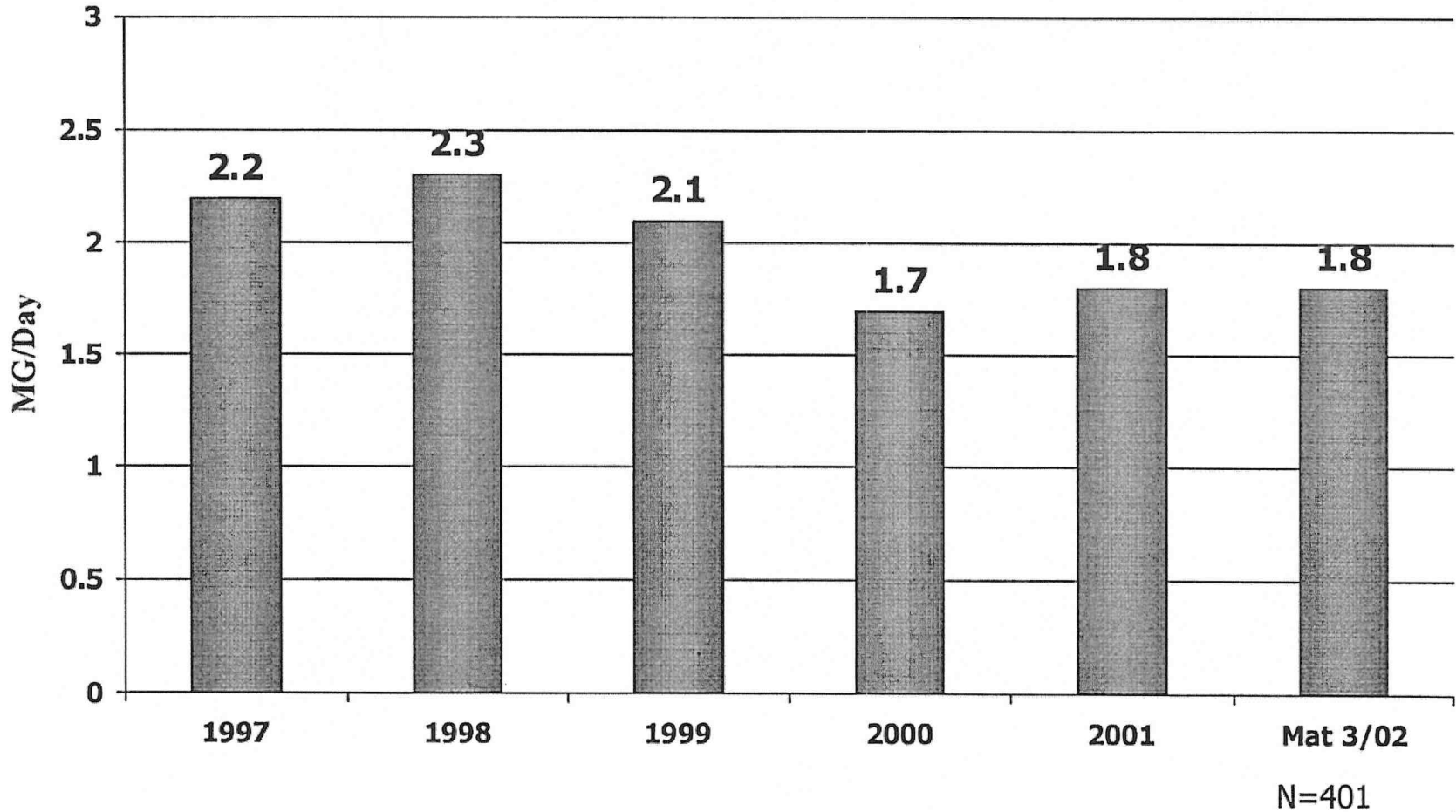
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# Risperdal C&A Dosing Trends

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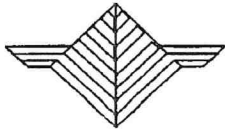


Subject to legal and regulatory review

Source: IMS Health, NDTI, MAT ending 1Q02  
Child and adolescent defined as ages 0-17

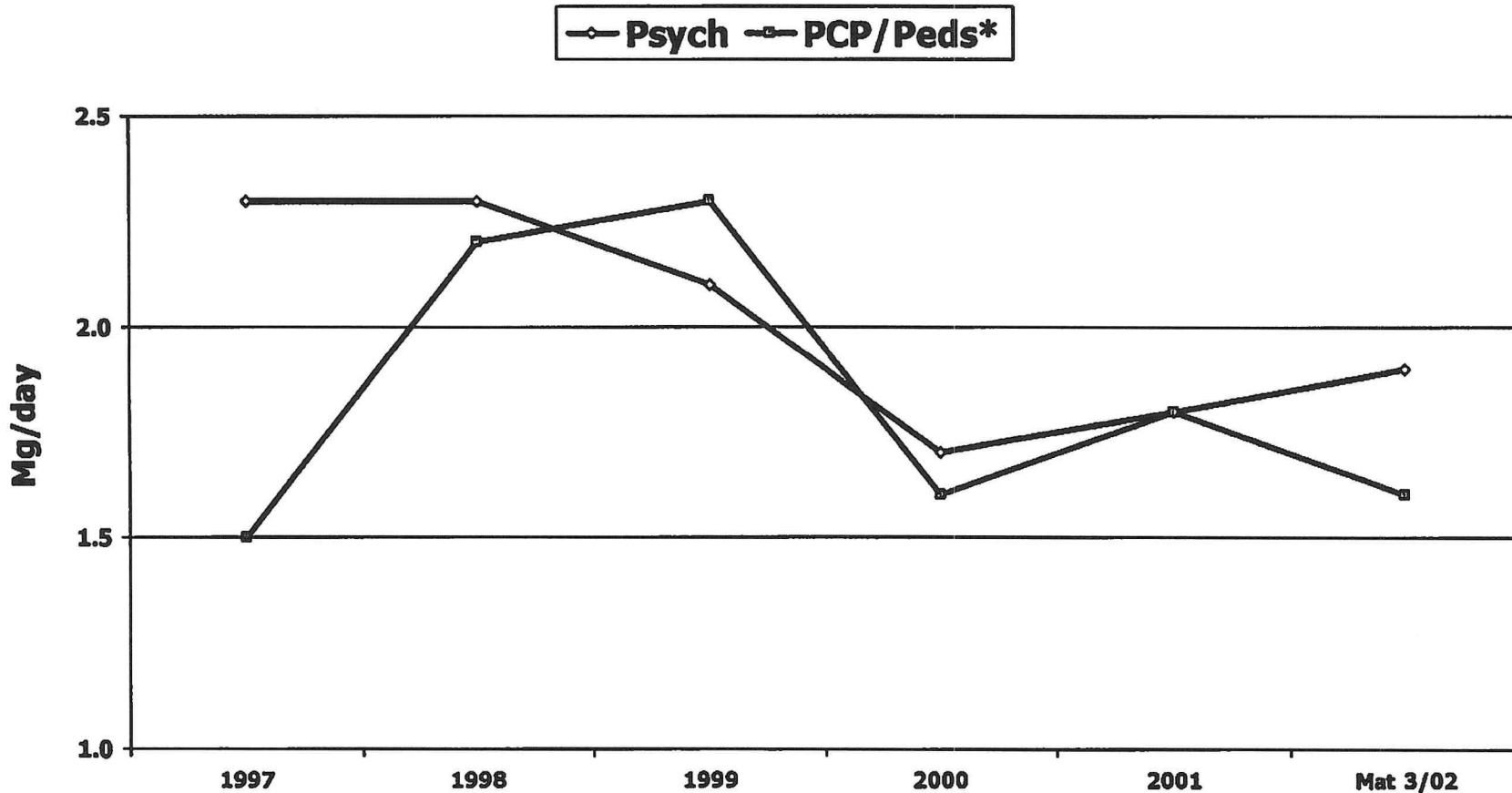
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# Risperdal C&A Dosing Trends by Specialty

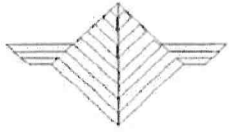
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Source: IMS Health, NDTI, MAT ending 1Q02, \*PCP/ Peds includes FP, GP, IM, DO, Peds

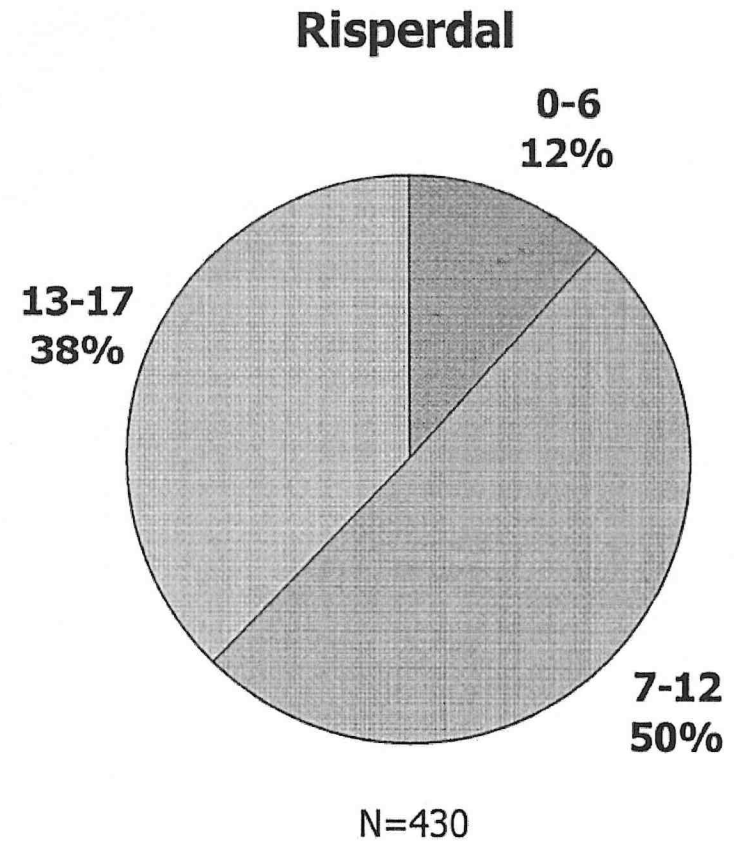
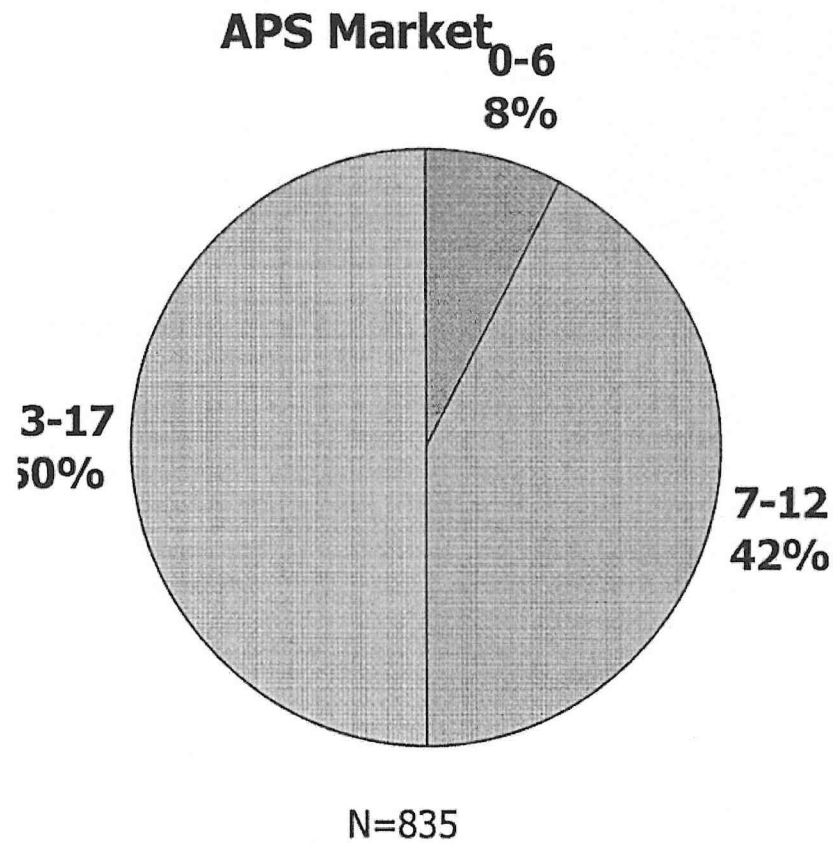
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Child and adolescent defined as ages 0-17

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# Child and Adolescent Age Breakdown

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Source: IMS Health, NDTI MAT ending 1Q02

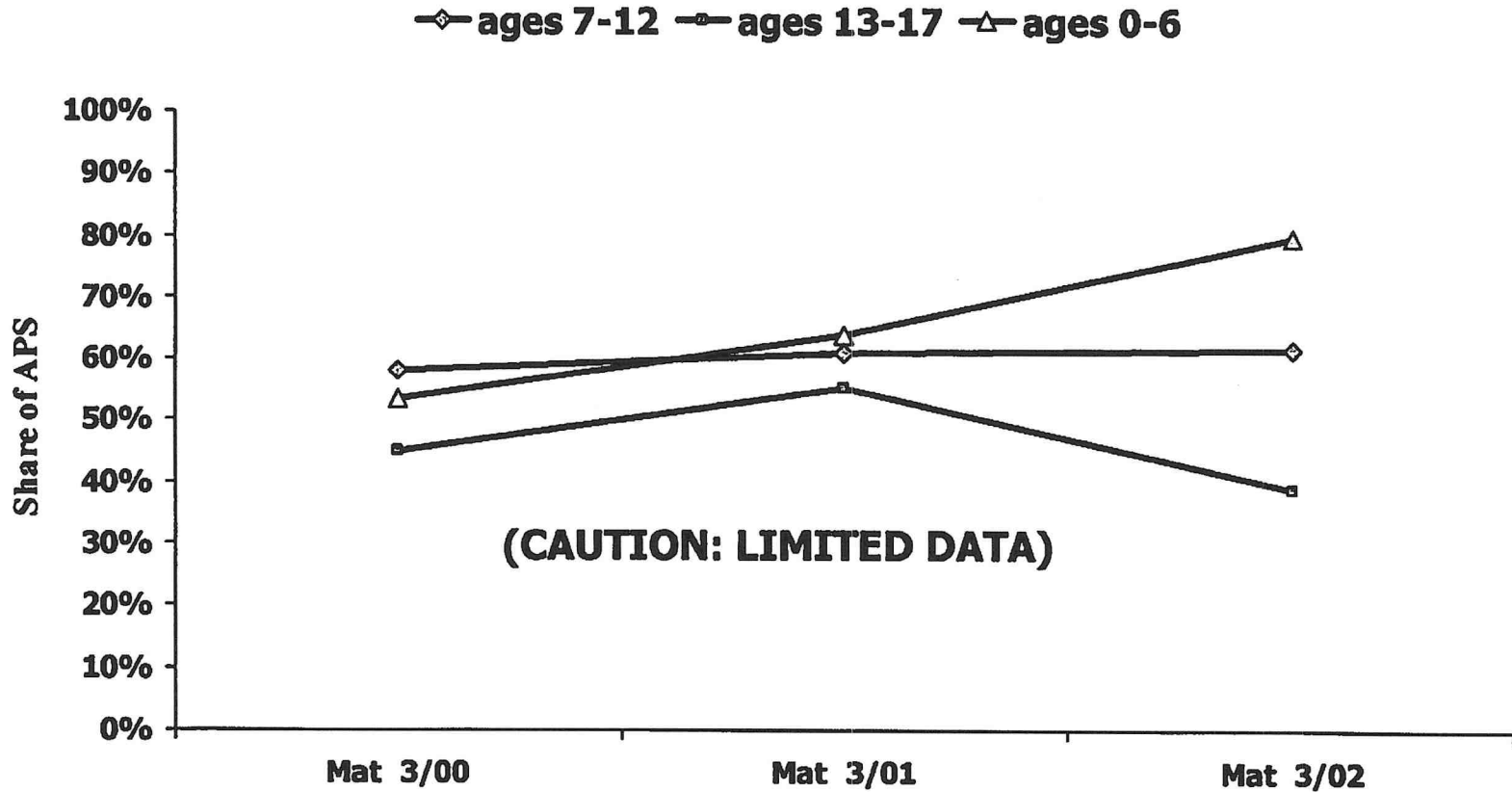
Child and adolescent defined as ages 0-17

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# Risperdal Share of C&A Age Groups

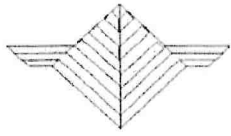


Source: IMS Health, NDTI MAT ending 1Q02

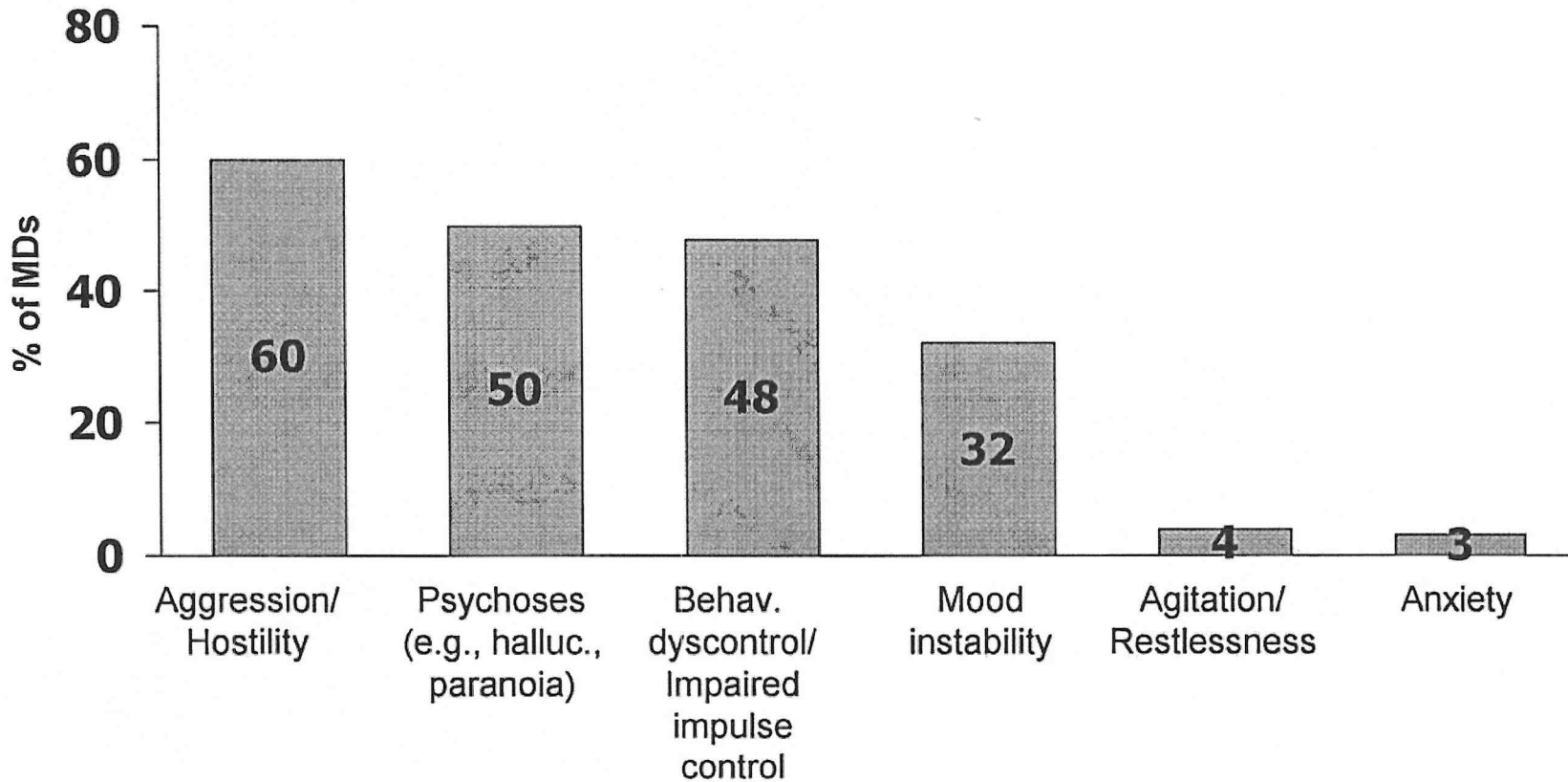
Child and adolescent defined as ages 0-17

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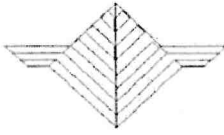


# TOP TWO C&A SYMPTOMS ADDRESSED WITH ANTIPSYCHOTICS

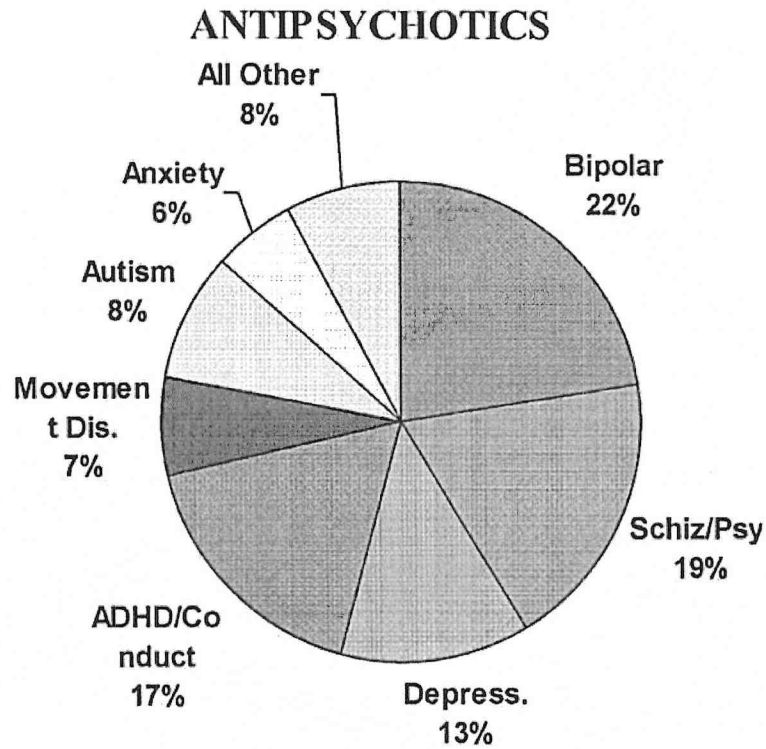


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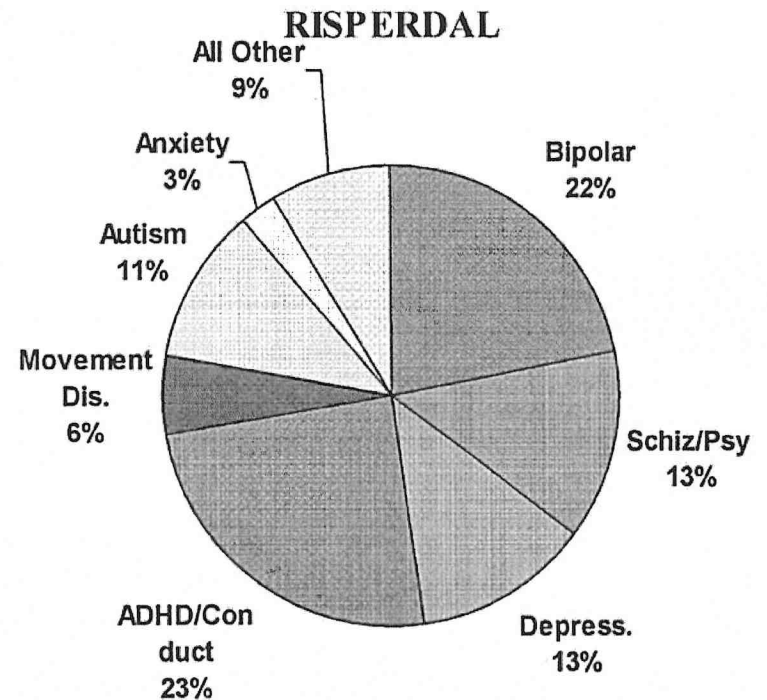
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# Antipsychotic Use In C&A Patients



N=848



N=436

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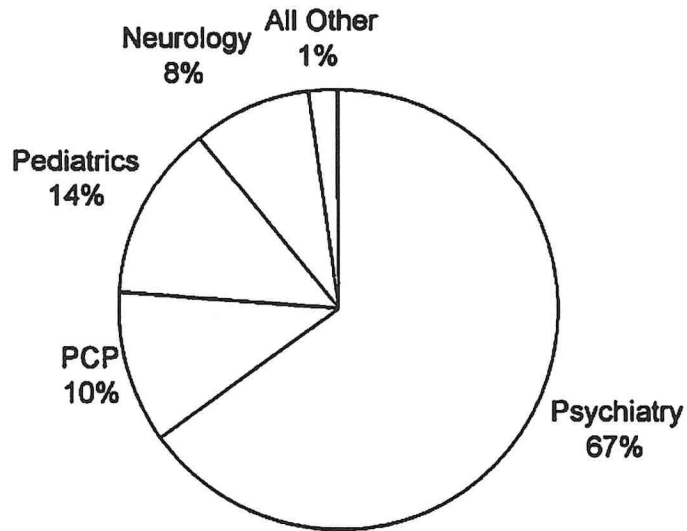
Source: IMS Health, NDTI, MAT ending 1Q02  
Child and adolescent defined as ages 0-17.

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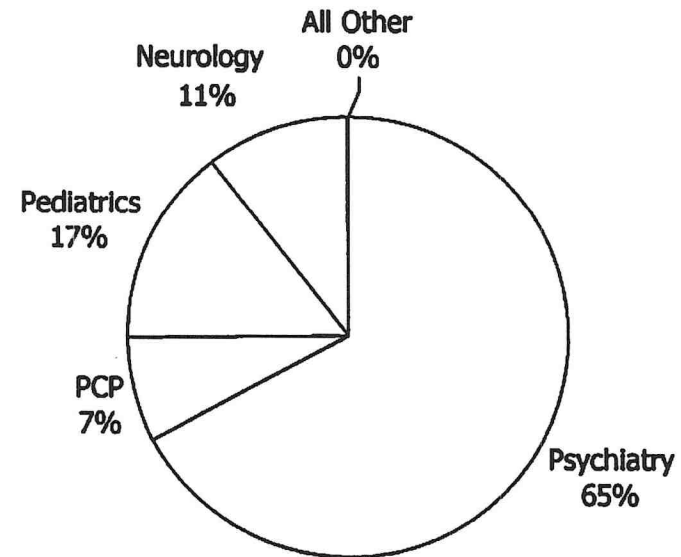
# Antipsychotic use by specialty in C&A patients

## ANTIPSYCHOTICS



N=1,006

## RISPERDAL



N=459

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Source: IMS Health, NDTI, MAT ending 1Q02  
Child and adolescent defined as ages 0-17

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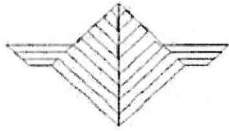


# Market Analysis Child Psychiatry Opportunity

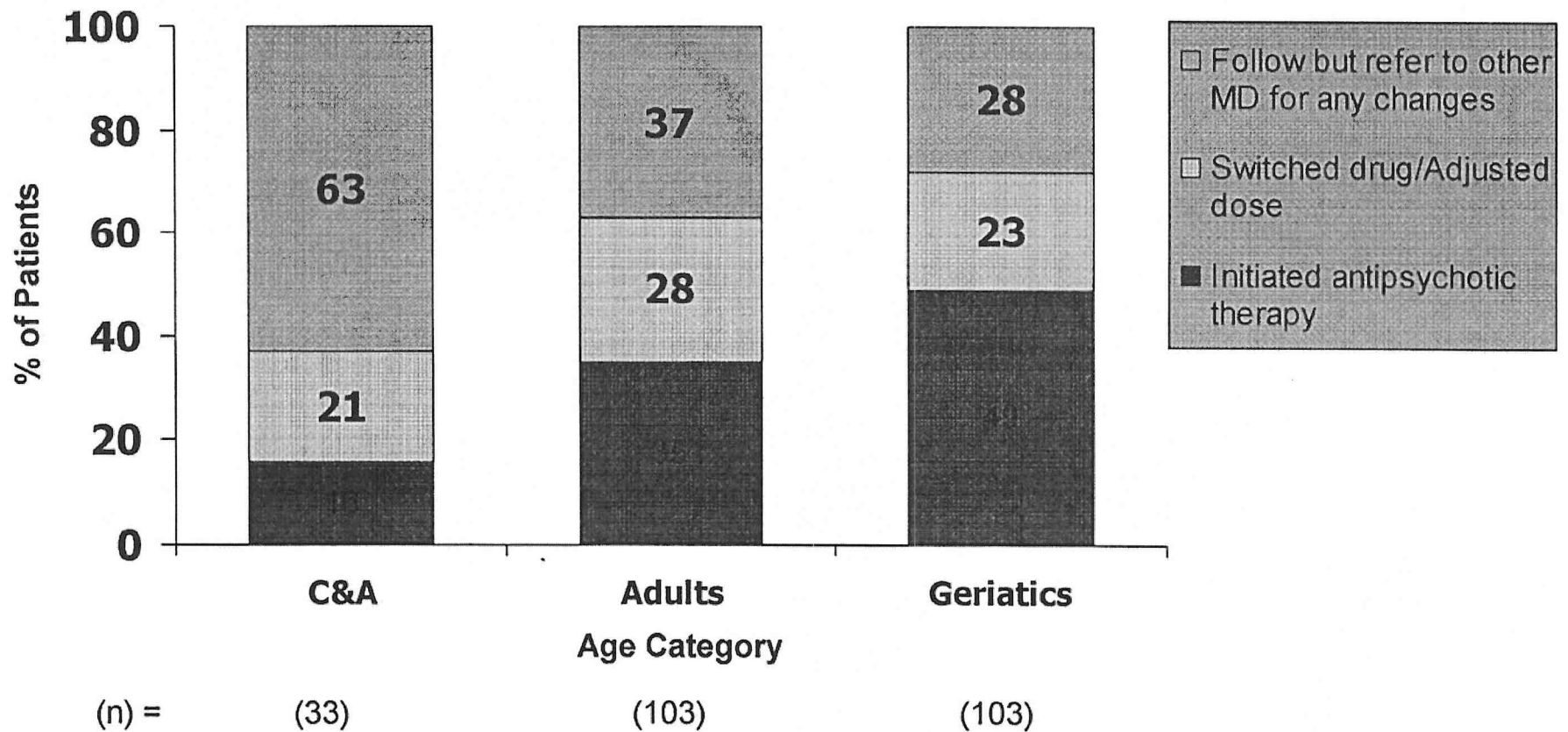
□ Number child psychiatrists		5,192
□ Cross Matched to APS Decile 20-90 (56.4%)		2,926
□ Cross Matched to APS Decile 50-90 (13.8%)		717
□ Received call last 12 months (63.7%)		3,307
> 1,985 received more than 12 calls (38.2%)		
> 30 APS 50 90CHPs received no calls		
□ Total APS Sales (Mar '01 - Feb '02)		\$311 MM
<u>Product</u>	<u>\$ Sales</u>	<u>NRx Share</u>
Risperdal	\$132 Million	42.5%
Zyprexa	\$69 Million	22.2%
Seroquel	\$53 Million	
17.1%		
Geodon	\$10 Million	3.2%
Conventionals	\$47 Million	15.1%

Subject to legal and regulatory review

Source: Powerplay cubes (Sales Force Optimization – Jan02 Decile Update), Janssen dollar sales 2003 *Business Plan*



# PCPs' Rate of Initiating/Changing Antipsychotic Treatment



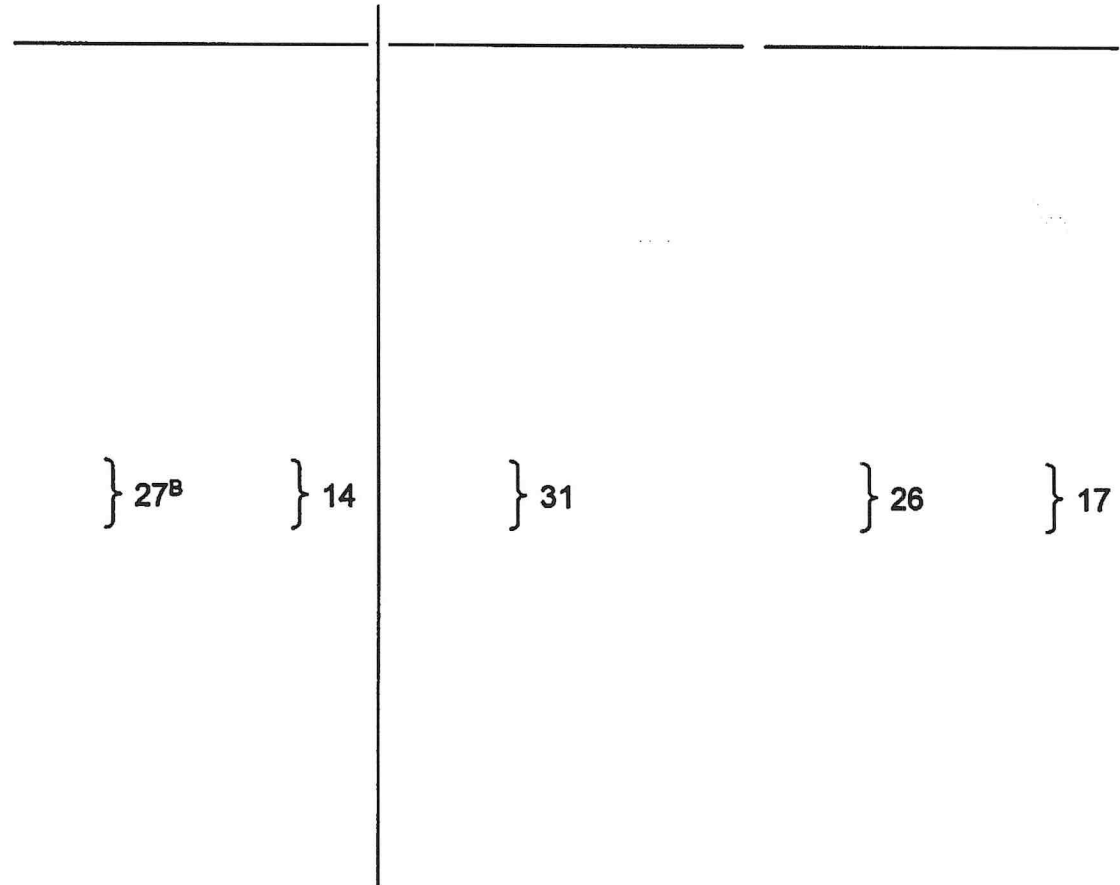
Subject to legal and regulatory review





# Top Three Diagnoses for APS RxING in C&A Disorders

**UNAIDED\***  
- Percent of MDs -



} 27<sup>B</sup>

} 14

} 31

} 26

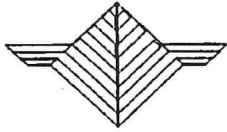
} 17

Q4 Base: Children/adolescents comprise at least 10% of their patients on antipsychotics

Subject to legal and regulatory review  
\*Mentioned by at least 5% of MDs

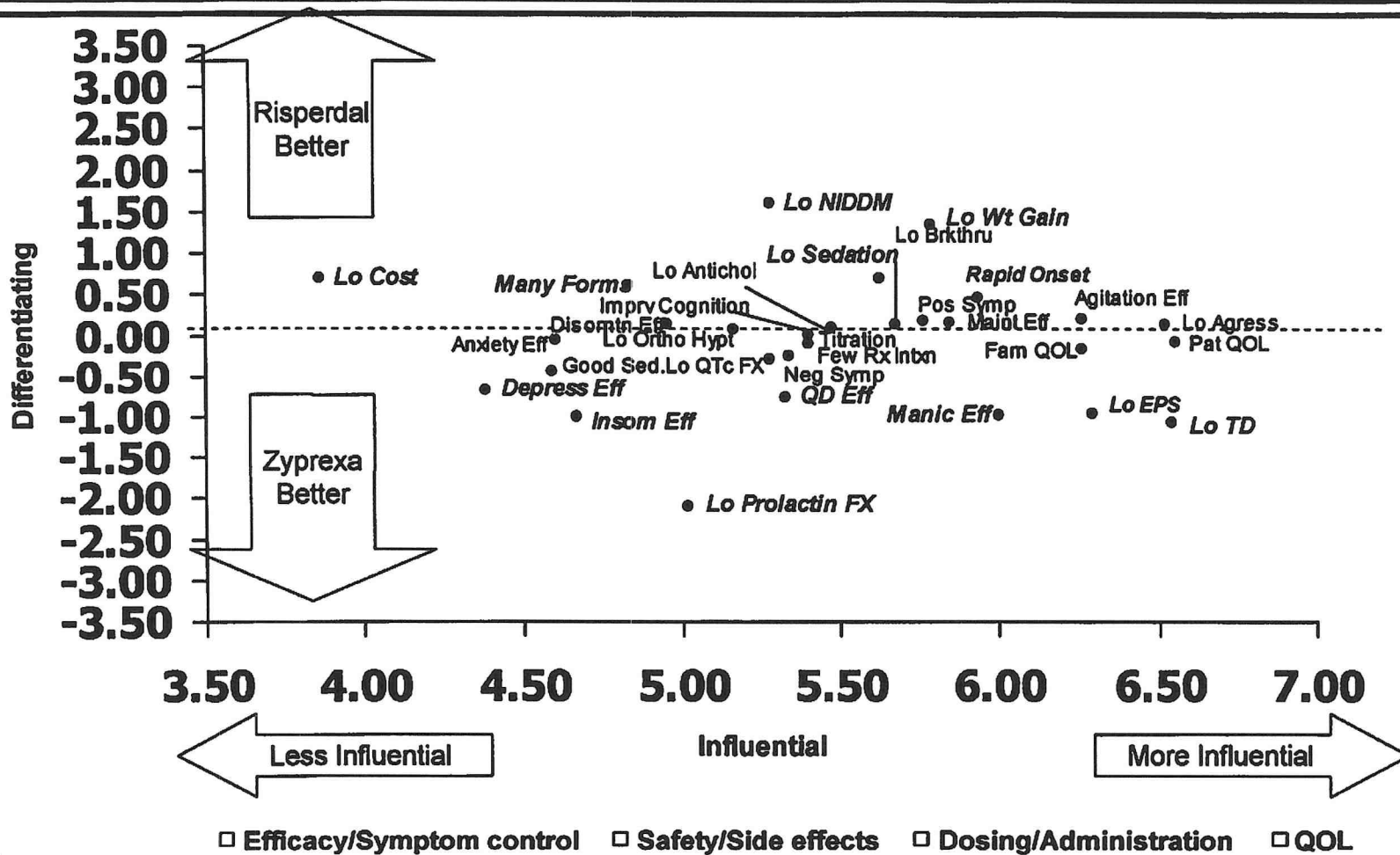
\*\*Caution, small sample size

2003 Business Plan



# RISPERDAL vs ZYPREXA For C&A Disorders 2002 - Psychiatrists

JJRE 02399447  
Confidential/Produced in Litigation Pursuant to Protective Order

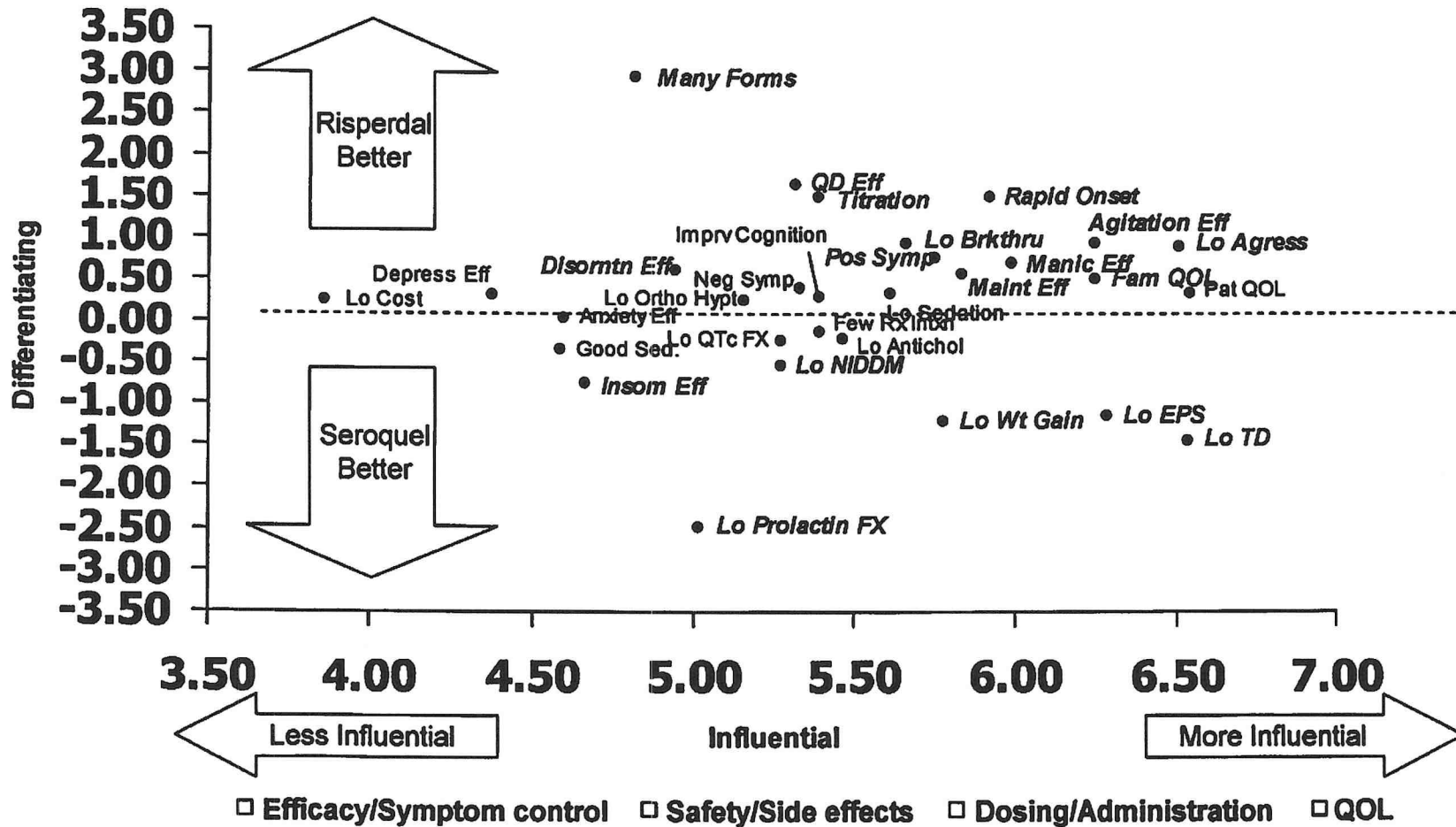


\*Subject to legal and regulatory review  
\*Attribute is bolded and italicized if significant difference between drugs.

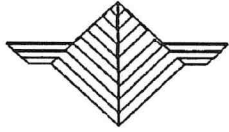
2003 Business Plan



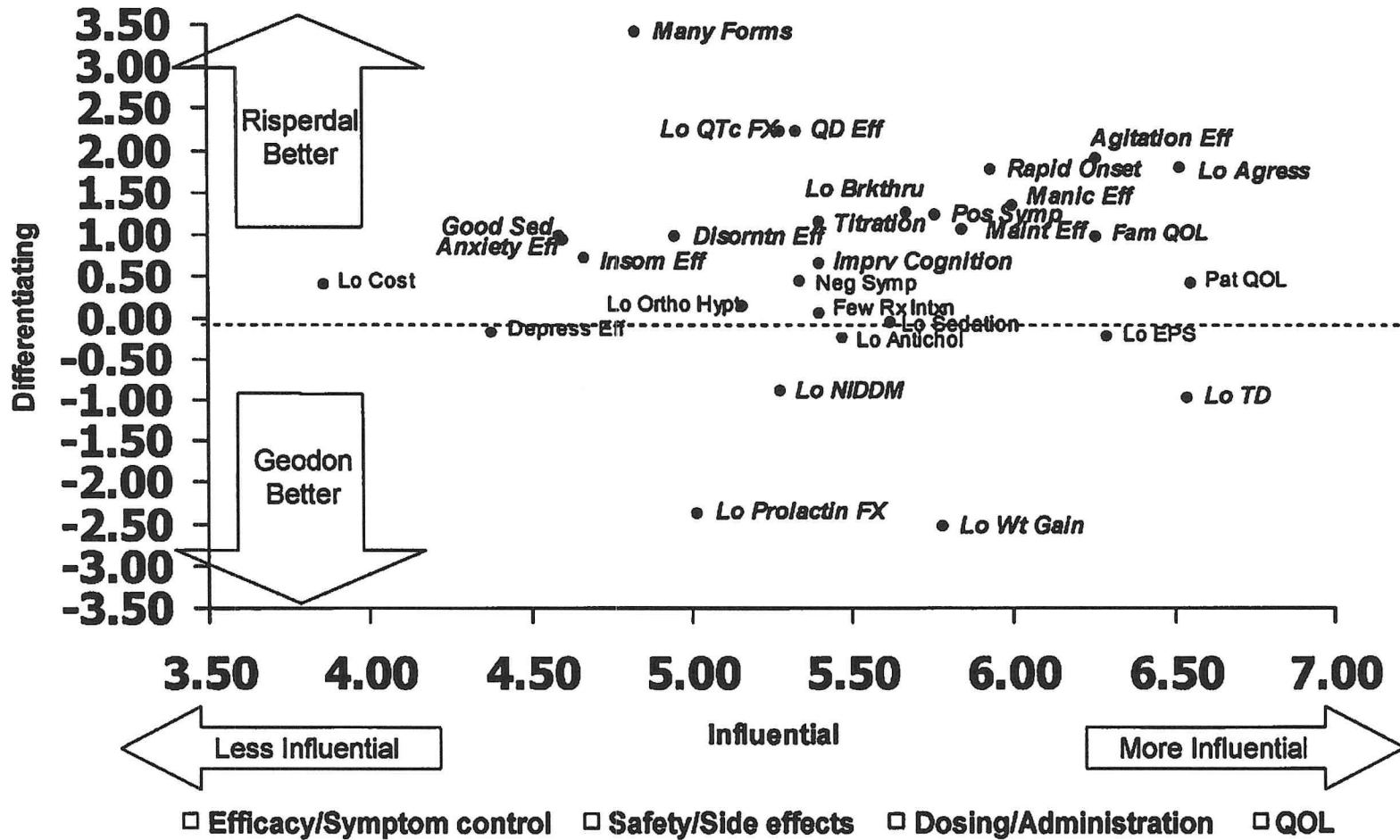
# RISPERDAL v SEROQUEL For C&A Disorders 2002 - Psychiatrists



\*Subject to legal and regulatory review  
\*Attribute is bolded and italicized if significant difference between drugs.



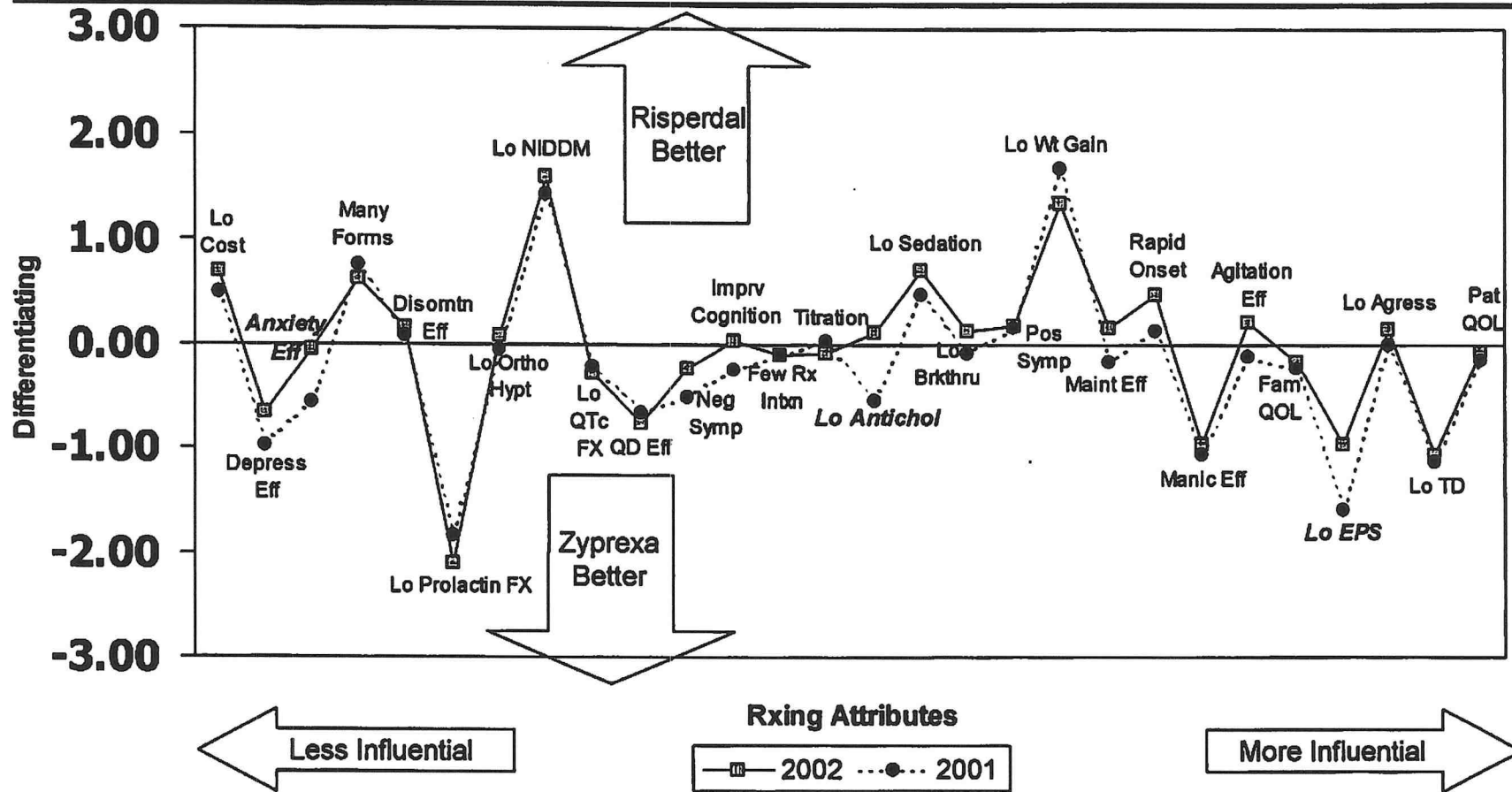
# RISPERDAL v GEODON FOR C&A Disorders 2002 - Psychiatrists



Subject to legal and regulatory review  
 \*Attribute is bolded and italicized if significant difference between drugs.



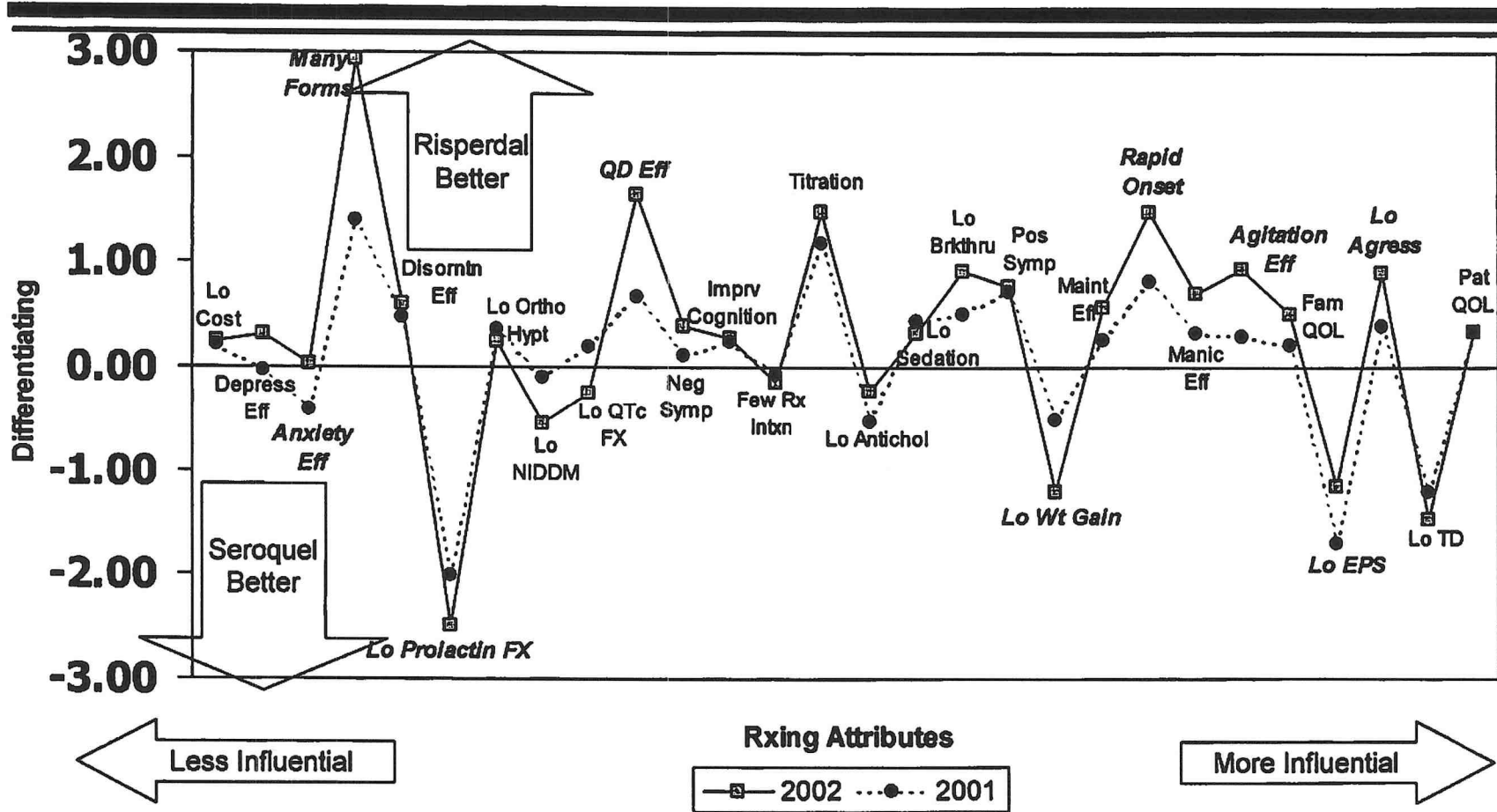
# RISPERDAL v ZYPREXA FOR C&A Disorders – 2001 v 2002 Psychiatrists



\*Subject to legal and regulatory review and italicized if significant wave difference



# RISPERDAL v SEROQUEL FOR C&A Disorders – 2001 vs 2002 - Psychiatrists



\*Subject to legal and regulatory review  
\*Attribute is bolded and italicized if significant wave difference