

Depakote®
New Psychiatry Markets
1998 Strategic Marketing Plan

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June, 1997

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Depakote®
New Psychiatry Markets
 1998 Strategic Marketing Plan- Table of Contents

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I. Executive Summary

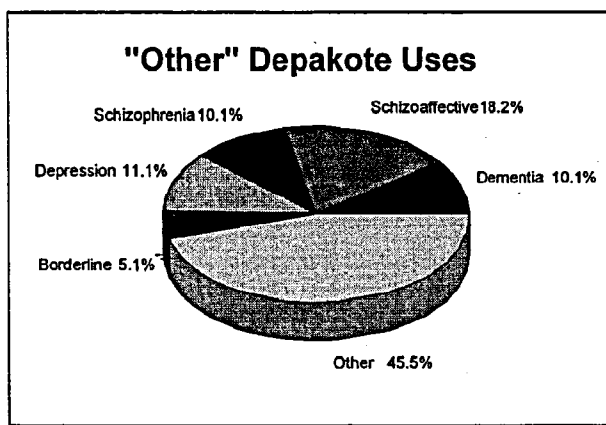
Depakote reached several significant milestones in the past 3 years. It received FDA indications for the treatment of bipolar disorder, migraine prophylaxis, complex partial seizures, and the approval of the intravenous formulation. The opportunities continue with the expected submission of Depakote CR later this year, and the potential to become a major player in 6 other disease states before the end of the millennium.

Abbott has made significant progress in the psychiatric market, establishing Depakote as the drug of choice in 2 out of 3 bipolar patient types. Depakote achieved about 30% of all new bipolar prescriptions in only 18 months post-FDA approval.

While Depakote gained clinical success among psychiatrists for bipolar disorder, psychiatrists began to utilize Depakote in patients with diagnoses which had no standard for treatment.

Recent data indicate that now more than 20% of all Depakote use is for "other" diagnoses. These diagnoses include: Behavior Disturbances Associated with Dementia, Schizoaffective Disorder, Depression, Substance Abuse, Schizophrenia, Borderline Personality Disorder, and Post-Traumatic Stress Disorder. These markets could add substantial commercial value to the brand and significantly improve the quality of life for many under served patient groups.

Clinical data suggest Depakote to be efficacious and well tolerated by patients in these various markets. In addition, these markets may assist in the introduction and long-term use of Abbott's new antipsychotic, Serlect™, as it may create a synergistic relationship with Depakote in several markets.



Estimated annual revenue just from the top four "other" uses of Depakote range from an additional \$400MM (base case) to \$900MM (upside) by year 2003. There is also a significant upside potential in defining and creating these "new" markets as they are significantly less risky than developing a new drug. Fortunately, Abbott will continue to enjoy Depakote patent protection through January, 2008.

Timing is of the essence. Competitive intelligence has indicated that several other pharmaceutical companies are aggressively pursuing these other markets. Early establishment of clinical efficacy may create standard treatment regimens in the absence of FDA approved pharmacotherapy.

Although opportunities exist in each of the new markets, this plan will focus on the two most promising markets- Behavior Disturbances Associated with Dementia and Schizoaffective Disorder.

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II. Situation Analysis- *Dementia with Behavioral Disturbance*

- By the year 2000, 35% of the population will be 65+ years of age and over 5 million people will be 85+ years of age. There are currently 15,600 nursing homes in the United States, with over 1.77 million beds and 1.6 million patients.
- The nursing home market is currently a \$1.8 billion drug market with an average of \$1,200 a bed spent on pharmaceuticals a year. Eight nursing home pharmacy providers control more than 60% of all nursing home beds. The typical nursing home patient is 75-80 years of age, takes 7-8 medications and will spend 180 days in the nursing home. Fifty-eight percent of all nursing home beds currently are controlled by chains.
- *Dementia* is characterized by the development of multiple cognitive deficits, including memory impairment plus disturbance in at least one other area such as aphasia, apraxia, agnosia, etc. Approximately 6% of people over the age of 65 manifest severe dementia, while an additional 10-15% are found to have mild to moderate cognitive impairment. Prevalence rates in nursing home populations have been reported at 30% for severe dementia and 80% for at least mild impairment. Alzheimer's disease is the most common type of dementia (45%) and multi-infarct or vascular dementia was the most second most common type (8-34%).
- *Agitation Associated with Dementia* is a common clinical problem. Of the 4.1 million patients with dementia in the United States, 2.9 million (70%) will have some form of behavioral disturbance. The prevalence has been reported in the literature to range from 43-93% of those with dementia. Only 2/3 of these patients will actually receive medication for the aggression/agitation. No medication is approved by the US Food and Drug Administration for the treatment of dementia-related behavioral disturbance. Nonetheless, the treatment of dementia-related behavioral disturbance usually includes psychotropic medications.
- Antipsychotics (39%) and benzodiazepines (10%) are the most commonly used agents, but beta-blockers, antidepressants (15%), lithium, Depakote (3%) and carbamazepine are also used. Only about 1/3 of patients will respond dramatically to the antipsychotics which are known to have a narrow therapeutic window between efficacy and adverse effects.
- Depakote use in this market has been growing consistently over the last three years to its current market share of 2.9%. The total market opportunity in Depakote dollars is \$204MM. Open label studies and case reports have concluded that Depakote is safe and effective for the aggressive/agitated behavior associated with dementia. The use of Depakote in this market is growing due to its broad spectrum of use across mood disorders, relatively benign side effect profile and few drug-drug interactions.

III. Key Objectives

A. *Penetrate the Long-Term Care Market to Drive Depakote Share*

- Market share for Depakote is lower in the Long-Term Care (LTC) setting than it is in the private sectors for all approved indications. In epilepsy, Dilantin currently has a 54% market share, Tegretol has a 17 % market share and Depakote has a 6% share (vs. 18% in the retail market). In bipolar, lithium has 68% of the market, Tegretol and Depakote both have a 10.4% share (vs. 32% in the retail market). Depakene/VPA have a 4.1% share in the epilepsy market and a 10.4% share in the bipolar market, which are also higher than in the private sector.
- Education of key decision makers and focused detailing efforts can significantly increase Depakote usage for all indications as well as decrease the rapidly increasing use of Depakene and generic valproic acid.
- New indications for Depakote in mania, complex partial seizures, migraine prophylaxis and new formulations including the controlled release formulation, and Depacon IV need to be promoted aggressively in the LTC market. The physicians, consultant pharmacists and nurses need to be educated about the correct dosing/monitoring , pharmacokinetics, pharmacodynamics as well as the adverse events profile of Depakote.
- Clinical data that demonstrate Depakote's effectiveness in treating aggression/agitation in elderly patients with dementia must be published. Competitive comparisons of other medications used in aggression/agitation need to be made to highlight Depakote's advantages.

B. *Obtain an FDA Indication for Dementia with Behavioral Disturbance*

- Conducting the clinical trials necessary to receive an NDA for Depakote in this market will result in both short-term and long-term sales growth for Depakote. Preliminary market research has shown that if Depakote were to achieve a 20% share of this market, fifth year sales could potentially reach \$100MM.
- The most commonly used drugs for aggression/agitation are the antipsychotics which are known to have numerous cognitive, sedative and EPS side effects. Due to its relatively benign side effect profile and few drug-drug interactions, Depakote can capitalize on the broad spectrum of efficacy in mood disorders to become positioned as a first-line choice for patients with dementia with behavioral disturbance.

C. Capitalize on OBRA Restrictions to Position Depakote as the Drug of Choice

- Depakote has a competitive advantage over neuroleptics, the most commonly prescribed drug for agitation/aggression in the elderly. In order for a patient to receive a neuroleptic in a nursing home:
 - ✓ Use of neuroleptic drugs must be documented as appropriate for the diagnosis.
 - ✓ Dose reduction and elimination of neuroleptic drugs must be attempted every six months.
 - ✓ Any drug must be used for the appropriate indication, dose, and duration.
 - ✓ Use must be adjusted based upon adverse events or drug interactions.
- Depakote can be prescribed without the above inconvenient and costly restrictions/guidelines that are an additional cost to the institution and provider.

D. Contract With Major LTC Pharmacy Providers to Drive Depakote Growth

- LTC Pharmacy Providers have the ability to influence therapy for the treatment of aggression/agitation in the elderly through formulary control and treatment protocols. By establishing relationships and agreements with these providers, Abbott can effectively drive market share of Depakote. Agreements can be forged by providing unrestricted educational grants to the providers in support of initiatives to educate pharmacists, physicians and nurses.
- Abbott also has the opportunity to guide the future treatment of this often ill-defined disorder by providing unrestricted grants for the development of consensus guidelines on the diagnosis and treatment of this disorder. Grants can be made to individual pharmacy providers or to various associations.

IV. Overall Positioning/Strategy/Message

- *Positioning*
 - ✓ Depakote will be positioned as the first-line choice for dementia with behavioral disturbance.
- *Core Strategy*
 - ✓ Establish Depakote as the first-line choice for dementia with behavioral disturbance due to its broad spectrum of efficacy, patient tolerability, lack of OBRA restrictions, convenient dosing, and a demonstrated 14 year track record.
 - ✓ Target education to high potential geriatric psychiatrists, medical directors, and other key customers.
 - ✓ Expand the number and scope of clinical studies to solidify Depakote's clinical role.
 - ✓ Establish Depakote as first-line treatment in practice guidelines of key

- ✓ pharmacy providers and managed care plans.
- ✓ Reinforce competitive advantages versus antipsychotics and benzodiazepines.

V. Key Strategic Issues

A. *The Market is Dominated by the Use of Neuroleptics/Antipsychotics*

- The major issue facing Depakote in this market is that it is dominated by antipsychotics, which currently have a 45% share of the market (approaching 20% for Risperdal). Physicians and pharmacists have used these drugs since the mid 1950's when they were first introduced. The key decision makers are comfortable with these medications. The traditional antipsychotics are now all generically available and thus, very inexpensive. Many patients with dementia are on the lower end of the socioeconomic scale and by virtue of their condition, lack insight, direction and resources to access newer drugs. Generically available drugs represent an affordable option.
- Risperdal has experienced rapid growth in the LTC market and continues to invest a significant amount of resources in promotional efforts, medical education and clinical trials. A new oral liquid was approved in late 1996 which potentially has broad applications for this market.
- Zyprexa will attempt to penetrate this market through significant investing of resources directed to clinical trials, medical education, journal advertising and focused detailing efforts. There is some question among thought leaders as to whether Zyprexa and the other novel antipsychotics will be classified by the OBRA guidelines, due to their perceived safety advantages over the traditional antipsychotics. [REDACTED] will also try to capitalize on a new indication for bipolar disorder expected in 1998.

B. *Abbott PPD has not Been a Major Player in the LTC Market*

- Historically, Abbott has not invested a significant amount of resources in the LTC market. Other companies such as [REDACTED], [REDACTED] and [REDACTED] have been very active in this market. [REDACTED] has been extremely active in the LTC market with Zoloft and now with the December FDA approval of Aricept (only the second drug to be approved for dementia associated with Alzheimer's disease). [REDACTED] is also conducting studies in the elderly with Ziprasidone, a new antipsychotic, expected to be approved in 1998.
- Abbott PPD has devoted a limited amount of managed health care resources to the LTC market, and has not developed the key relationships our competitors have.

Ross has established relationships with most of the key organizations in LTC, and were one of the founders of the American Medical Directors Association fifteen years ago.

C. Depakote Market Share in the LTC Setting is Lower in all Therapeutic Segments Than it is in the Overall Market

- The market share for Depakote is significantly lower in the LTC market for bipolar disorder and epilepsy than it is in the private sector. The market leaders, Dilantin and lithium, are older drugs that physicians and pharmacists are more comfortable with. The high prescribers in this setting tend to be primary care doctors that have not taken part in medical education initiatives in this arena. Safety concerns, specifically hepatotoxicity, are issues which have not been addressed adequately with this target audience.
- The main competitors in the aggression/agitation market are the traditional antipsychotics which physicians have used since the 1950's. REDACTED also has spent considerable amounts of funding to educate the target audience on the product profile of Risperdal.
- Lack of education, safety concerns and questions about proper dosing and drug interactions are hindering the use of Depakote for dementia with behavioral disturbance.

D. Key Decision Makers in the LTC Setting are not Familiar with Depakote

- Consultant pharmacists, key decision makers in the LTC market have not been targeted in the past with information or educational materials about Depakote. Relationships with the American Society of Consultant Pharmacists have been initiated but not developed to a great extent.
- Geriatric psychiatrists have not been targeted in the past with medical education about the broad spectrum of Depakote's efficacy in mood disorders.
- Medical directors of nursing homes have not been targets for medical education initiatives by Abbott on Depakote and are consequently more comfortable prescribing the older medications for aggression/agitation in the elderly.
- High anticonvulsant prescribing GP/FP/IM physicians are now beginning to be called on by NSRs on a limited basis. These physicians are being detailed by both REDACTED and REDACTED on the use of Risperdal and Zyprexa in aggression/agitation in the elderly.

E. *FDA Obstacles May Exist to Pursuing an Indication for Aggression/Agitation*

- REDACTED M.D., Director, Division of Neuropharmacological Drug Products, FDA, has written a letter to Abbott dated January 28, in response to an Investigational New Drug Application (IND) submitted by Abbott in regards to the protocol for M96-491, "A Double-Blind, Placebo-Controlled, Study of Valproate in the Treatment of Behavioral Agitation Associated with Dementia." The letter clearly states that aggression/agitation will not be an approvable indication for divalproex. He also explains that at this time there is no diagnostic validity (except for dementia, of which agitation is one of the symptoms) and that there is no agreed therapeutic target or measure for aggression/agitation in the elderly. However, the FDA did recommend the feasibility of extending the existing antimanic claim to the elderly.
- Per discussions with several opinion leaders, competitors in this market are aggressively moving forward to conduct the studies necessary to get an indication for this market with the expectation that the FDA may alter its position towards a potential approval.

VI. **Strategies to Address Key Issues**

A. *The Market is Dominated by Neuroleptics/Antipsychotics*

- Drive home the Depakote message to key decision makers.
- Foster the need to improve compliance to medication through Depakote usage. Depakote's side effect profile is clearly superior to all of the traditional antipsychotics and does not have the EPS side effects of Risperdal and Zyprexa.
- Ensure that Depakote achieves competitive share of voice; focus on key customer segments, including high prescribers (psychiatry and primary care), pharmacy providers, consultant pharmacists and nurses.
- Utilize publication and education efforts to drive home the superior efficacy and safety of Depakote versus antipsychotics and benzodiazepines.
- Establish Depakote as more cost-effective than the antipsychotics in the overall disease management approach of treating aggression/agitation.
- Develop treatment algorithms for dementia with behavioral disturbance.

B. *Abbott PPD Has Not Been a Major Player in the LTC Market*

- Abbott has begun the initial step by dedicating a National Manager for LTC as well as a product manager focusing on a potential indication for dementia with behavioral disturbance for Depakote.
- PPD can capitalize on the expertise and influence that Ross has with the major players in this market to expand awareness of Depakote.
- Provide educational grants to key organizations in this market to develop relationships/guidelines (AMDA, AAGP, ASCP).
- Dedicate focused detailing on top LTC targets.

C. *Depakote's Market Share is Lower than it is in the Community in all Therapeutic Categories*

- Drive home Depakote message to key decision makers including consultant pharmacists, medical directors of nursing homes, and geriatric psychiatrists.
- Medical education initiatives
- Focus on the broad spectrum of Depakote in mood disorders
- Develop opinion leaders in the LTC market. This is essential in facilitating rapid market share growth for Depakote. Abbott has established strong relationships with many key national psychiatric thought leaders, but needs to increase it to include both national and regional experts across specialties of primary care physicians, consultant pharmacists and directors of nursing in LTC.
 - ✓ Expand relationships through NMLs, sales and marketing management
 - ✓ Support involvement in marketing and venture funded clinical trials
 - ✓ Support medical education opportunities
- Improve the diagnosis of dementia with behavioral disturbance

D. *Key Decision Makers in the LTC Market are not Familiar with Depakote*

- Identify and target the high prescribing primary care physicians to disseminate and communicate Depakote product information.
- For each of the key decision makers (medical directors, consultant pharmacists and high prescribing GP/FP/IM)
 - ✓ Identify their role in the treatment decision
 - ✓ Utilize geropsychiatrists, consultant pharmacists, medical directors in developing CME initiatives outlining the diagnosis and treatment of dementia with behavioral disturbance.

- ✓ Establish non-personal initiatives outlining the core message for Depakote to these key individuals/organizations.

- Capitalize on other indications for Depakote by pooling resources for medical education initiatives

E. *Regulatory Obstacles May Exist to Pursuing an FDA Indication for Aggression/Agitation*

- Meet with the FDA to discuss concerns and issues related to an approval for aggression/agitation
- Establish support from opinion leaders as to the need for consensus guidelines on the diagnostic criteria, targets and measures for a potential aggression/agitation claim.
- Conduct a clinical trial in elderly patients with mania to file for a claim extension for mania and include a large percentage of patients with dementia.
- Clinically examine if Depakote may improve cognition in Alzheimer patients as an alternative strategy for a potential FDA indication.

I. *Situation Analysis- Schizoaffective Disorder*

- Approximately 1% of the U.S. population, or 2.6MM people, suffer from schizoaffective disorder. At most, 50% of schizoaffective patients, or 1.3MM people, currently receive treatment.
- Based on 1996 NDTI data for drug uses, antipsychotics dominated the relevant market with a 43% share. This includes risperidone with 9.4%, Haldol with 3.5%, and olanzepine with 1.4% in only three months. Anticonvulsants consisted of 13% of total drug uses, led by Depakote with a 7.9% share, and followed by klonopin with 2.7% and carbamazepine with 2.6%. Lithium consisted of 8.6% of all drug uses. Other classes of drugs used to treat schizoaffective disorder include SSRIs (11%), anti-Parkinson agents (5.9%), tri/tetracyclics (4.2%), and benzodiazepines (3.5%). The total market is estimated to be worth approximately \$200MM in Depakote dollars.
- Because schizoaffective disorder consists of both schizophrenic and bipolar symptoms, products in both these areas are relevant for treating the disease and are often administered concurrently.
- The availability of clearly defined diagnostic criteria for schizoaffective disorder

has allowed significant improvement in the reliability of its diagnosis in recent years. In two studies which used such specific operational criteria to assess its diagnostic reliability, diagnostic agreement for schizoaffective disorder was comparable with that for bipolar disorder and schizophrenia.

- According to DSM-IV, schizoaffective disorder consists of an uninterrupted period of illness during which there is either a major depressive episode, a manic episode, or a mixed episode concurrent with symptoms for schizophrenia, such as delusions or hallucinations. Approximately half of those affected suffer from the bipolar subtype where the disturbance includes a manic or mixed episode (schizoaffective mania), while the remainder suffer from the depressive subtype where the disturbance only includes major depressive episodes.

II. Key Objectives

A. Obtain an FDA Approval for the Treatment of Schizoaffective Disorder

- Conducting the clinical trials either to receive an NDA for Depakote in this indication or to publish results citing Depakote's efficacy will result in both short-term and long-term sales growth for Depakote. Preliminary market research has shown that if Depakote were to achieve a 25% share of this market, fifth year sales could reach more than \$100MM.
- In recent studies, depakote improved psychotic symptoms in bipolar patients and preliminary data supports depakote's efficacy in both schizoaffective disorder and schizophrenia. Depakote could be positioned as a monotherapy for schizoaffective disorder.

B. Educate Psychiatrists Regarding Depakote's Efficacy

- Currently, psychiatrists have not been systematically informed or educated on the benefits of using Depakote to treat schizoaffective disorder. Doing so through education initiatives or the publication of articles/studies in relevant journals will contribute to short-term and long-term growth for Depakote.
- Additionally, as psychiatrists become more aware of Depakote as a treatment for schizoaffective disorder, they will be more comfortable in diagnosing patients who may otherwise be diagnosed with schizophrenia or a mood disorder and prescribing Depakote as the treatment of choice.

III. Overall Positioning/Strategy/Message

- *Positioning*
 - ✓ Depakote will eventually be positioned as the first-line choice for schizoaffective disorder.

- *Core Strategy*
 - ✓ Eventually establish Depakote as the first-line choice for schizoaffective disorder due to its broad spectrum of efficacy, patient tolerability, lack of side effects associated with antipsychotics, convenient dosing, and a demonstrated 14 year track record.
 - ✓ Target aggressive education to high potential psychiatrists, and other key customers.
 - ✓ Establish Depakote as first-line treatment in practice guidelines
 - ✓ Reinforce competitive advantages versus lithium, Tegretol and other new mood stabilizers.

IV: Key Strategic Issues

A. *Lack of Market Research*

- Currently, primary and secondary data for the schizoaffective market is not readily available to track Depakote Rx's or to precisely analyze the marketplace.

B. *Credibility in the Diagnosis of Schizoaffective Disorder is Building*

- Traditionally, schizoaffective disorder frequently was viewed as a temporary condition as a sufferer progressed either into schizophrenia or bipolar disorder. Relatively recent research has shown that schizoaffective disorder is not part of a continuum, but rather an independent disease state with a unique clinical course and outcome. This notion is building among psychiatrists, but the traditional view is still held by many practitioners.

V. Strategies to Address Key Strategic Issues

A. *Lack of Market Research*

- Coordinate efforts with the Market Research department to investigate methods to track Depakote Rx's in schizoaffective disorder as well as the historic, current, and future competitive environment. Conduct primary research to understand the perceptions of psychiatrists, pharmacists, patients, and other key players for use in making better marketing decisions regarding segmentation and positioning.

B. *Credibility in the Diagnosis of Schizoaffective Disorder is Building*

- Work with opinion leaders and other relevant constituencies to build credibility in schizoaffective disorder as an independent disease with specific symptoms and treatments. Teach psychiatrists and other practitioners how to use the standard operational diagnostic criteria that now exist.
- Develop treatment algorithms for schizoaffective disorder and explore the possibility of eventually co-promoting Depakote with an atypical antipsychotic, preferably Serlect, but perhaps Risperdal (REDACTED) or Zyprexa (REDACTED).

Appendix I:
Situation Analysis Support
Dementia with Behavioral Disturbance
Schizoaffective Disorder

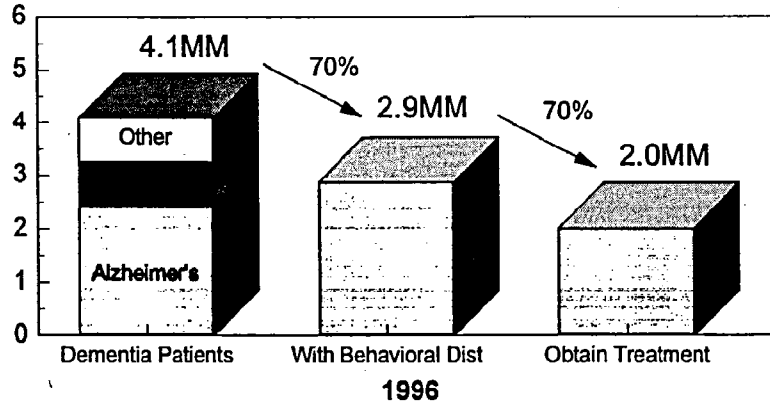
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Dementia with Behavioral Disturbance Patient Population

10-15% of the U.S. Population Over Age 65 Has Dementia
MM



Source: Population Profile of the U.S., relevant literature.

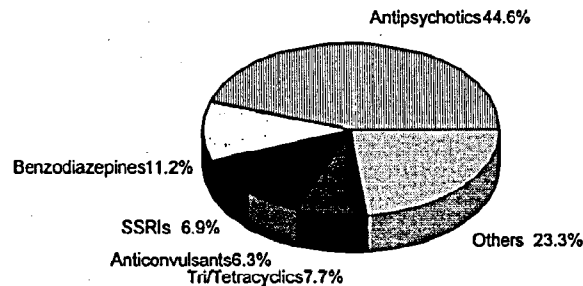
Competitive Situation

Dementia with Behavioral Disturbance

% Drug Use by Type

June 1995 thru May 1996

Total Market in Depakote Dollars: \$203.6MM



Source: NDTI.

Current Depakote Market Share: 2.9%

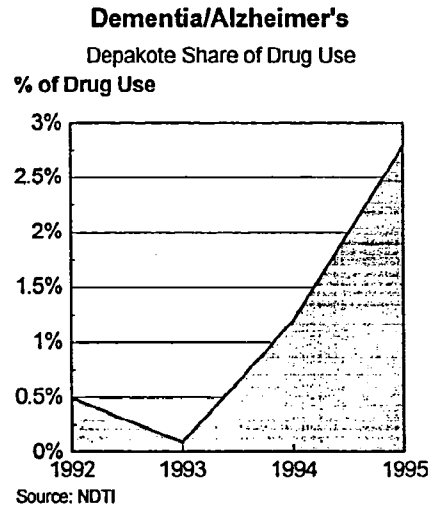
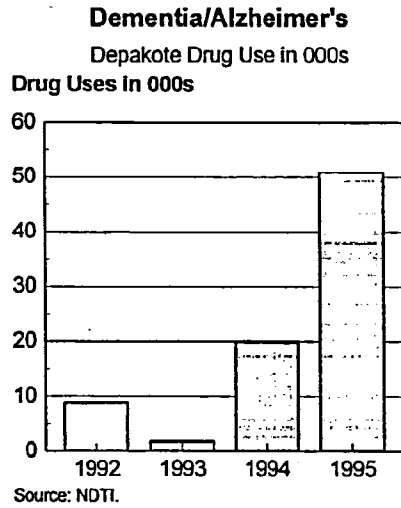
Drug Uses = 1,915,000

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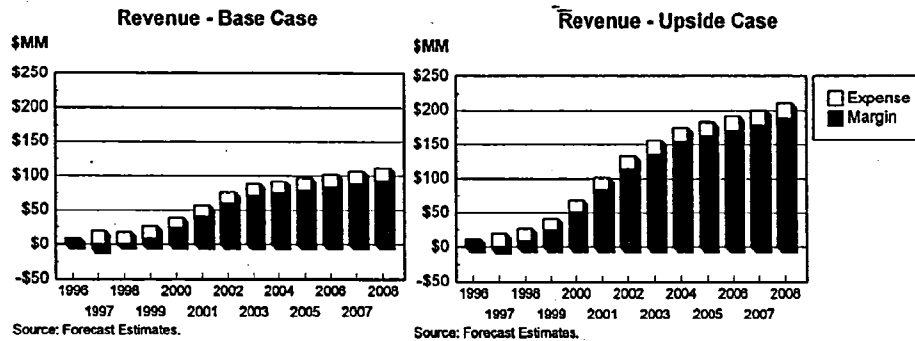
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Depakote Use for Dementia with Behavioral Disturbance



Dementia with Behavioral Disturbance Market Forecast

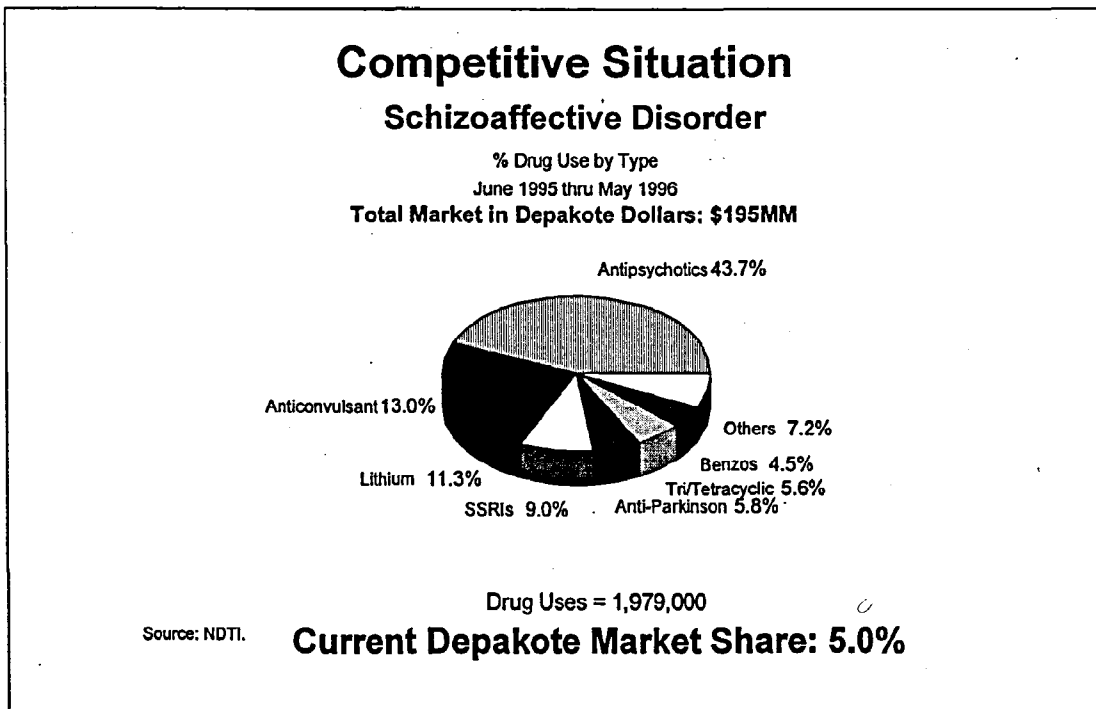
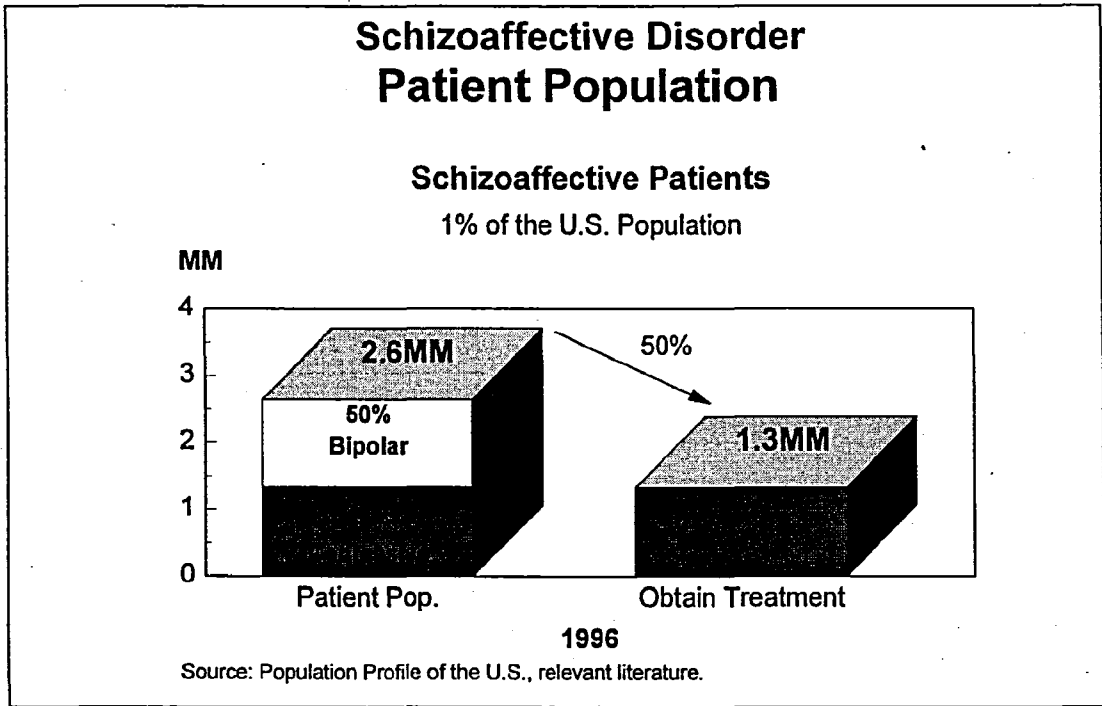


	Base Case	Upside Case
Assuming FDA Approval in July, 1999		
5th Year Sales in 2003	\$88.8MM	\$156MM
5th Year Contribution Margin	\$71.5MM	135.7MM
NPV @ 15% (1996-2005, After-Tax)	\$77.1MM	\$163.0MM

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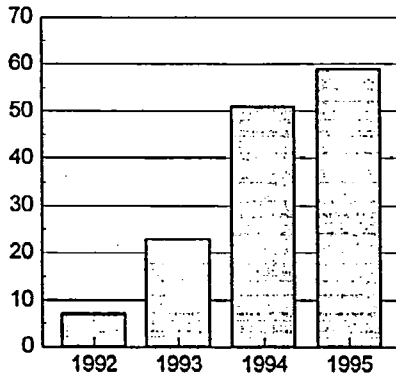
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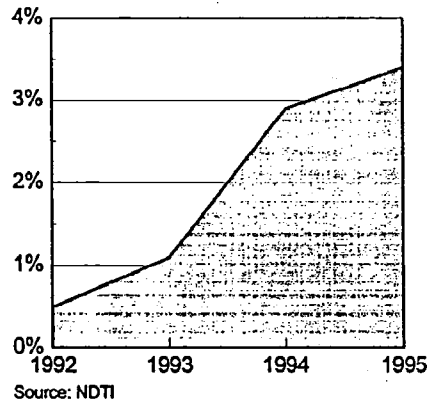
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Depakote Use for Schizoaffective Disorder

Schizoaffective Disorder
Depakote Drug Use in 000s
Drug Uses in 000s

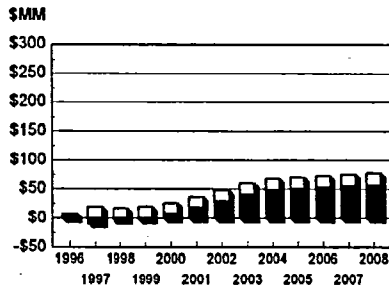


Schizoaffective Disorder
Depakote Share of Drug Use
% of Drug Use

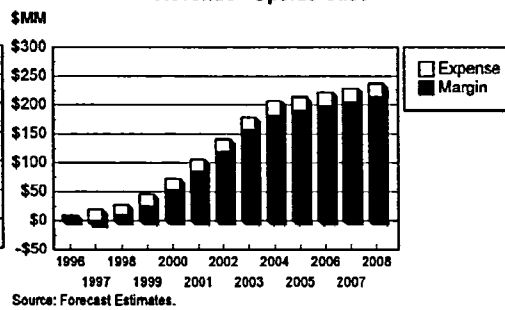


Schizoaffective Disorder Market Forecast

Revenue - Base Case



Revenue - Upside Case



	Base Case	Upside Case
Assuming FDA Approval in July, 1999		
5th Year Sales in 2003	\$60.2MM	\$179.6MM
5th Year Contribution Margin	\$40.9MM	\$157.1MM
NPV @ 15% (1996-2005, After-Tax)	\$34.1MM	\$179.3MM

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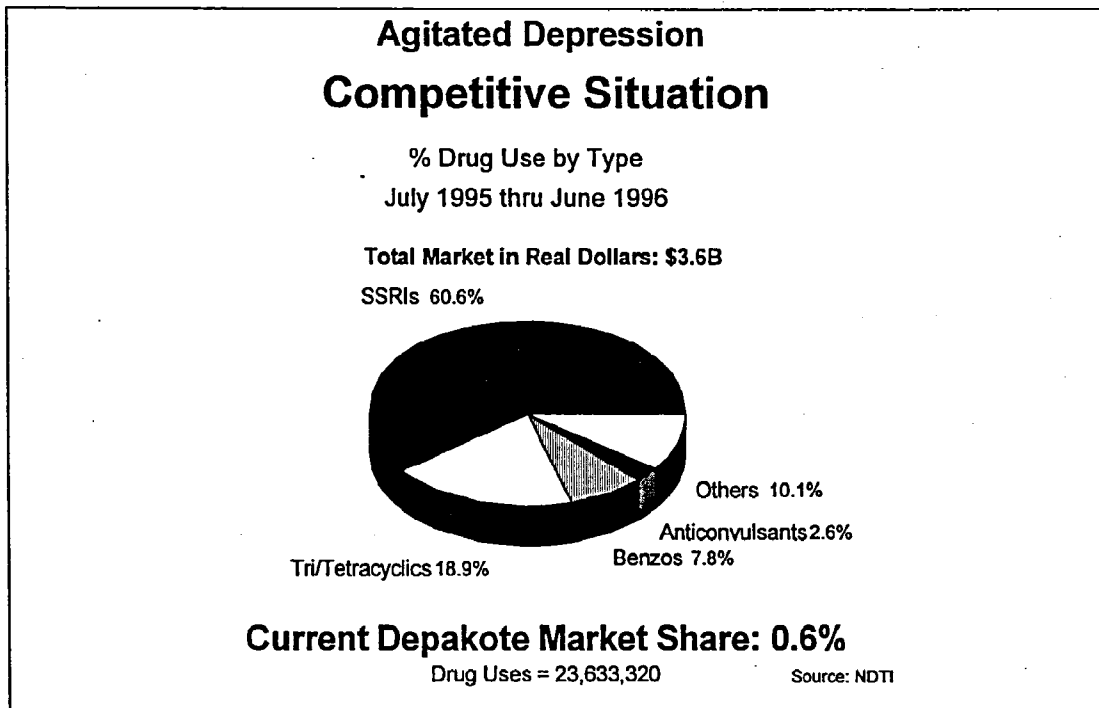
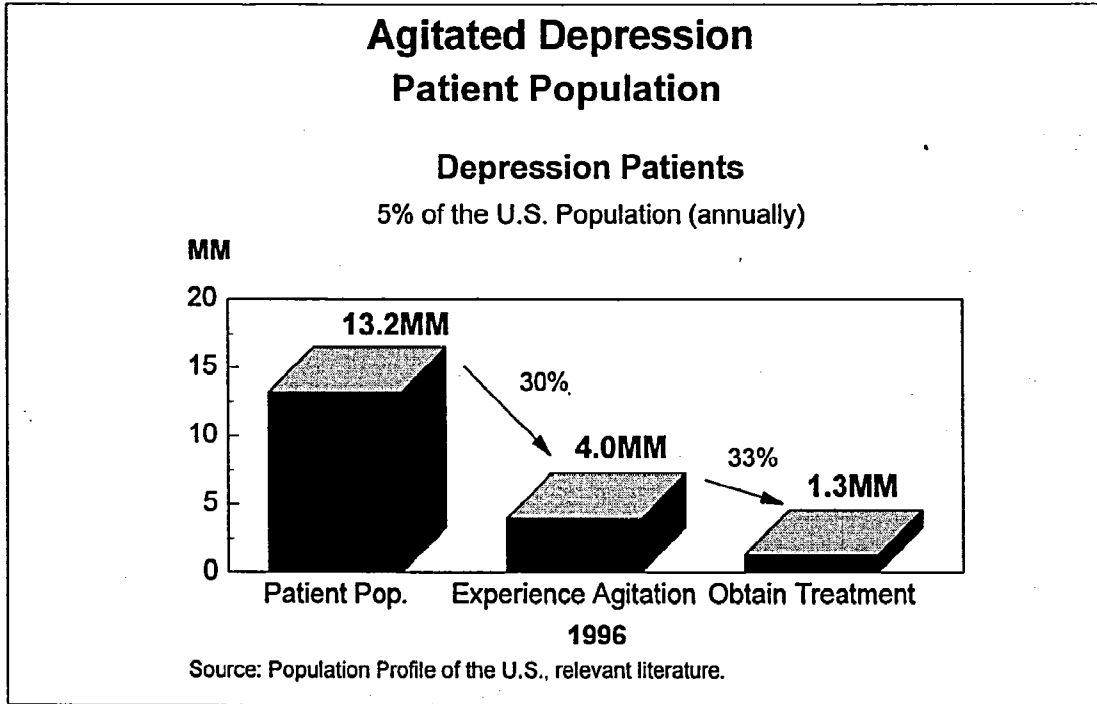
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Appendix II:
Other Market Opportunities
Market Size/Potential by Disease State & Patient Population Breakdown
Agitated Depression
Borderline Personality Disorder
Substance Abuse
Post-Traumatic Stress Disorder

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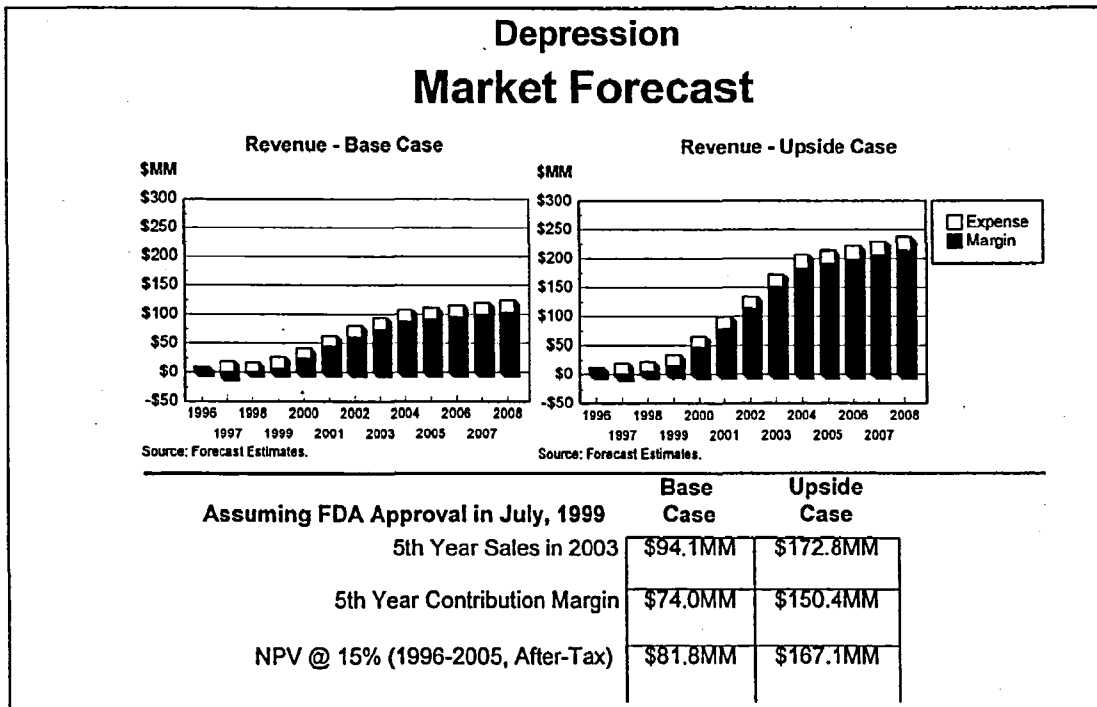
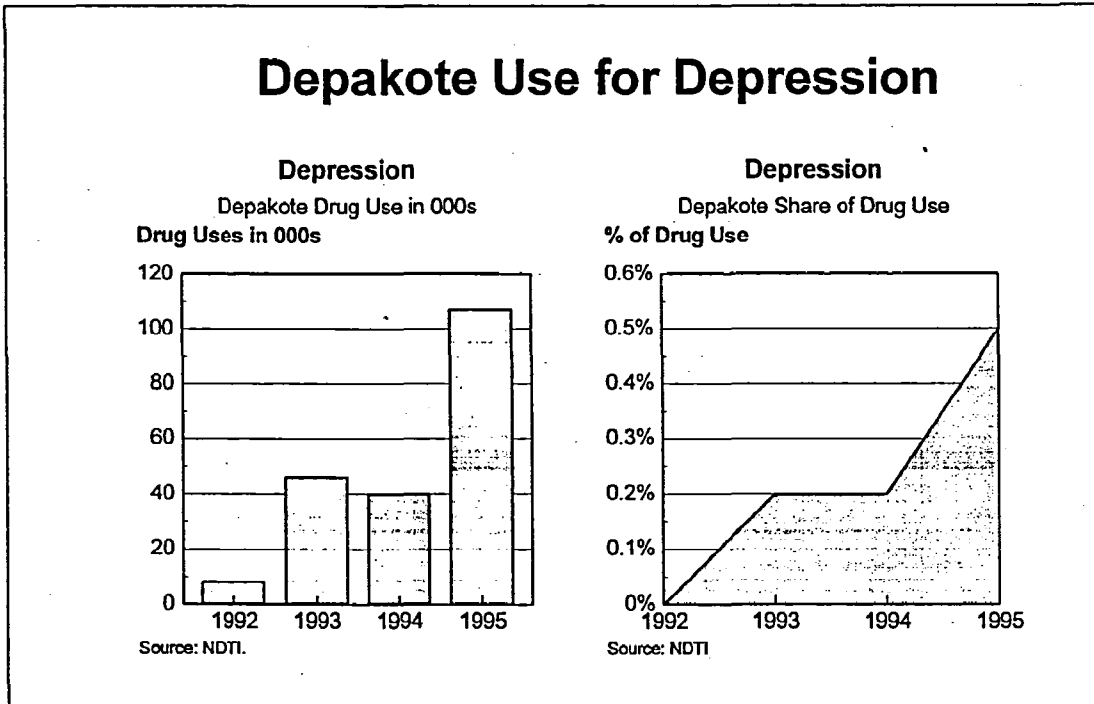
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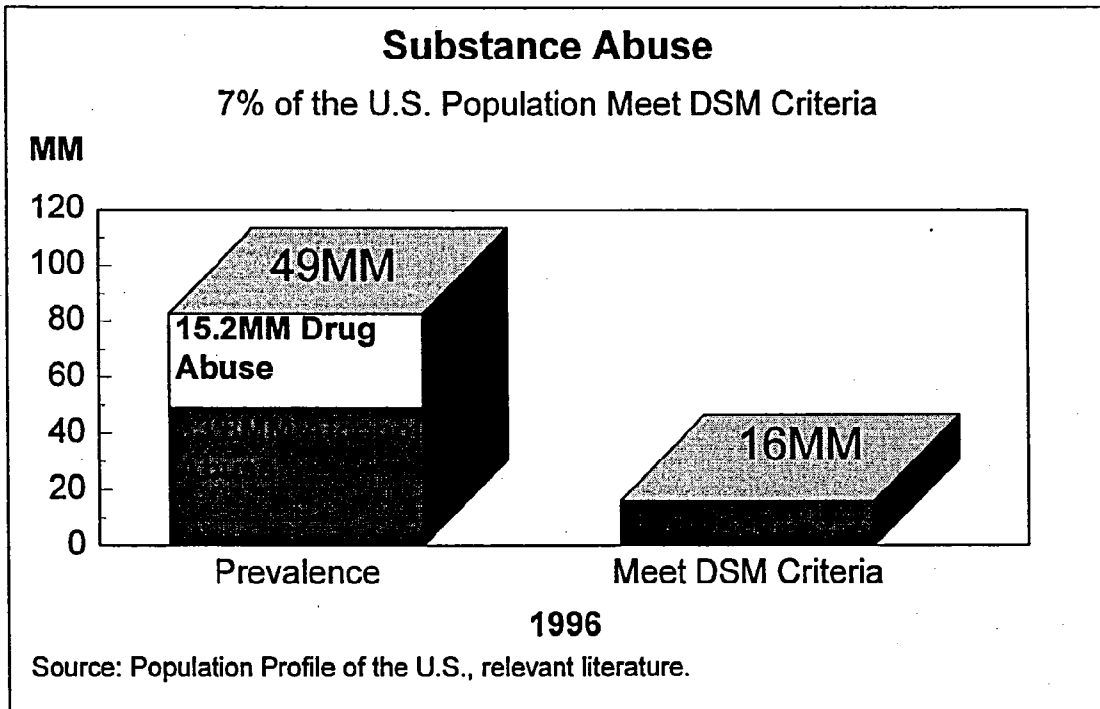
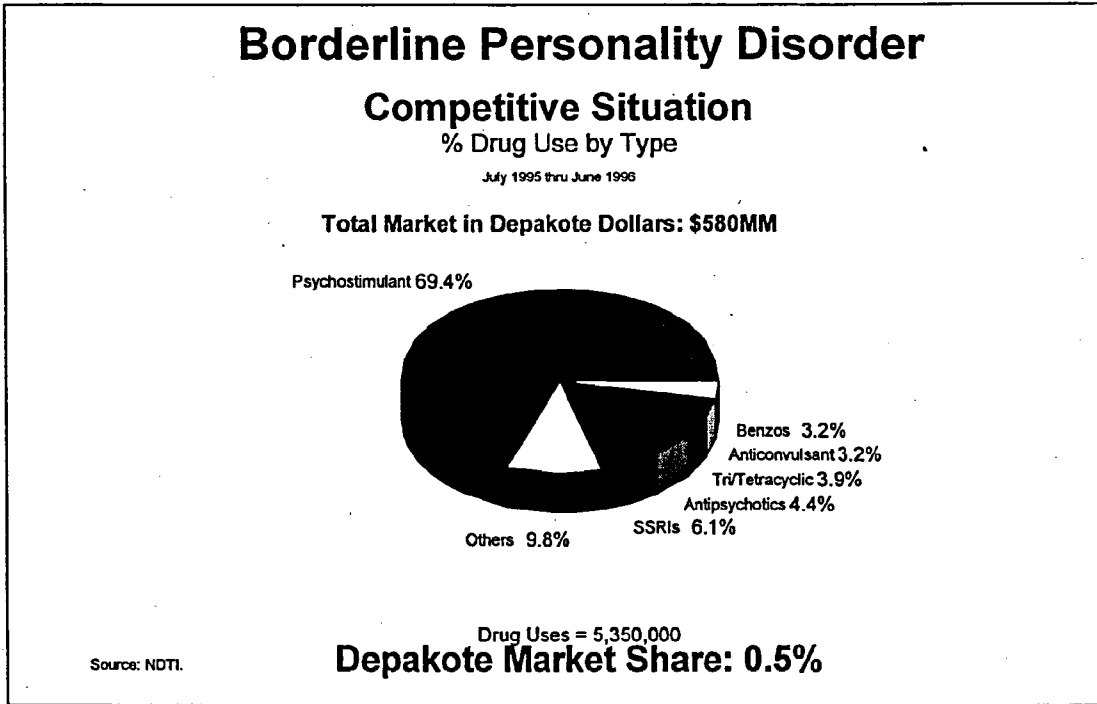
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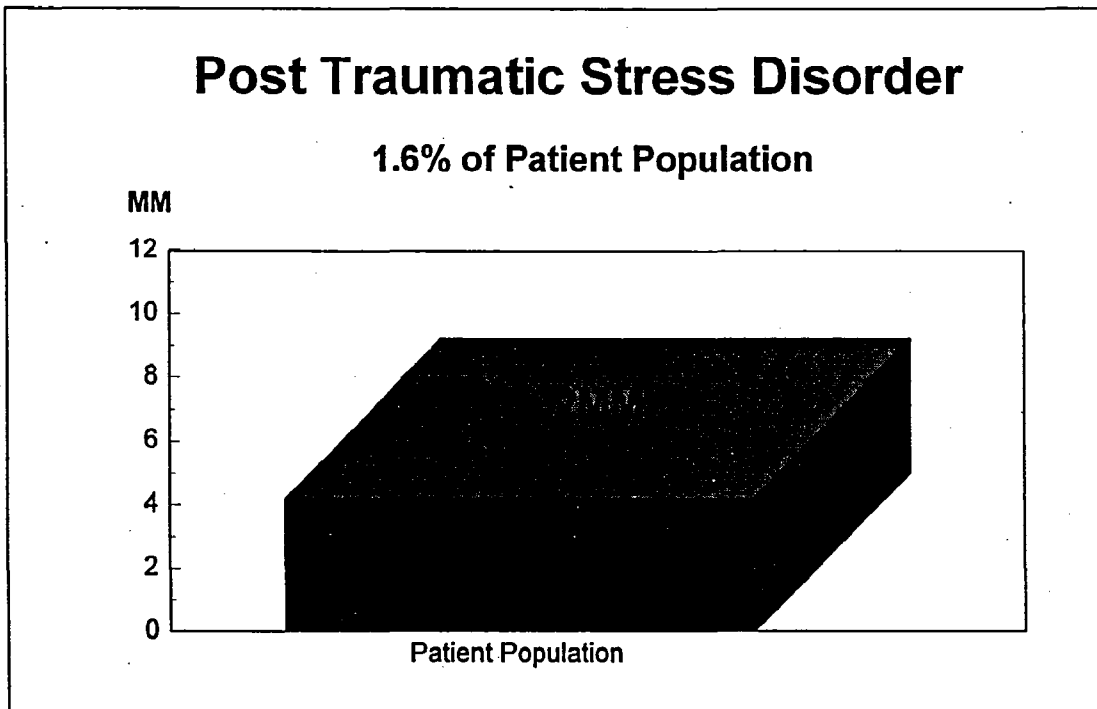
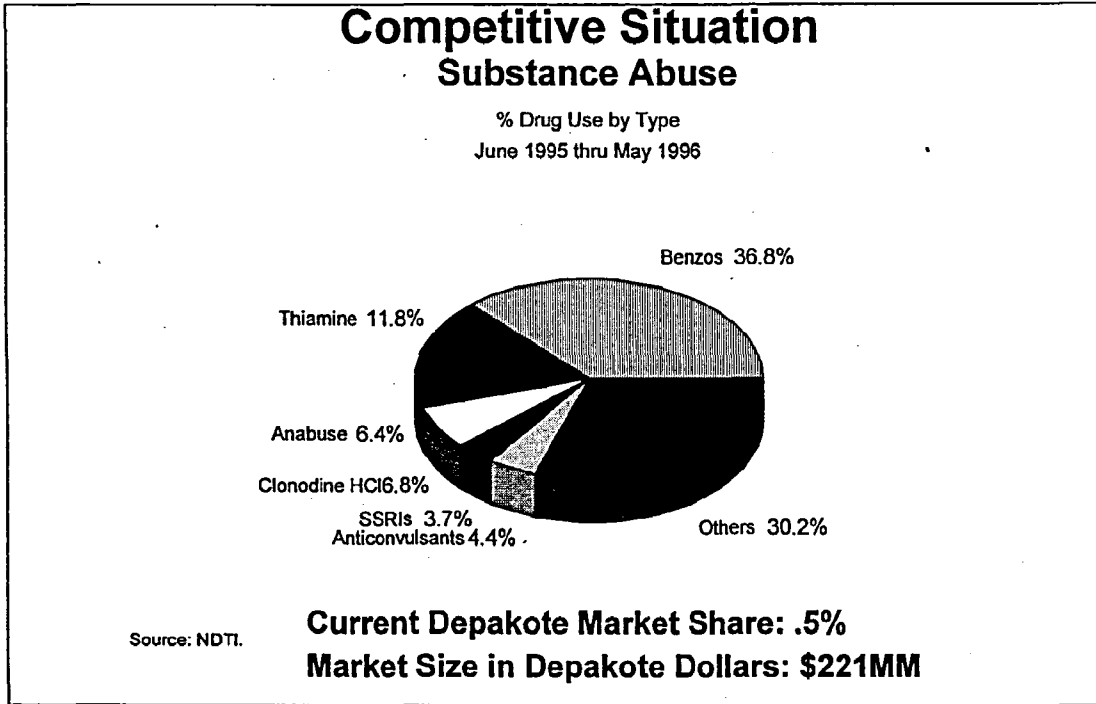
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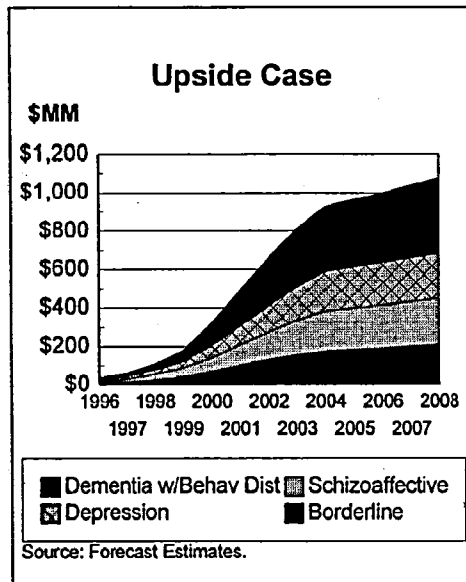
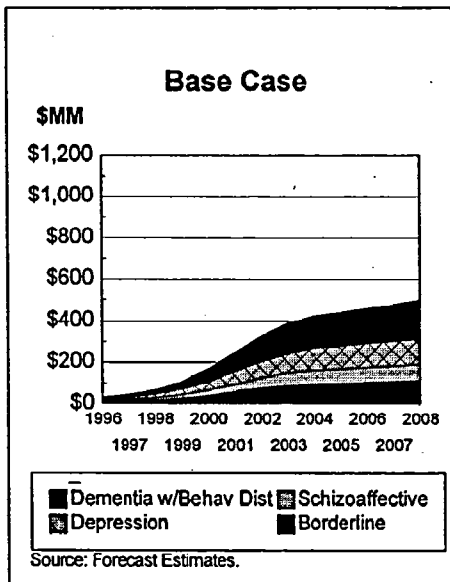


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Estimated Revenue from 4 New Indications



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