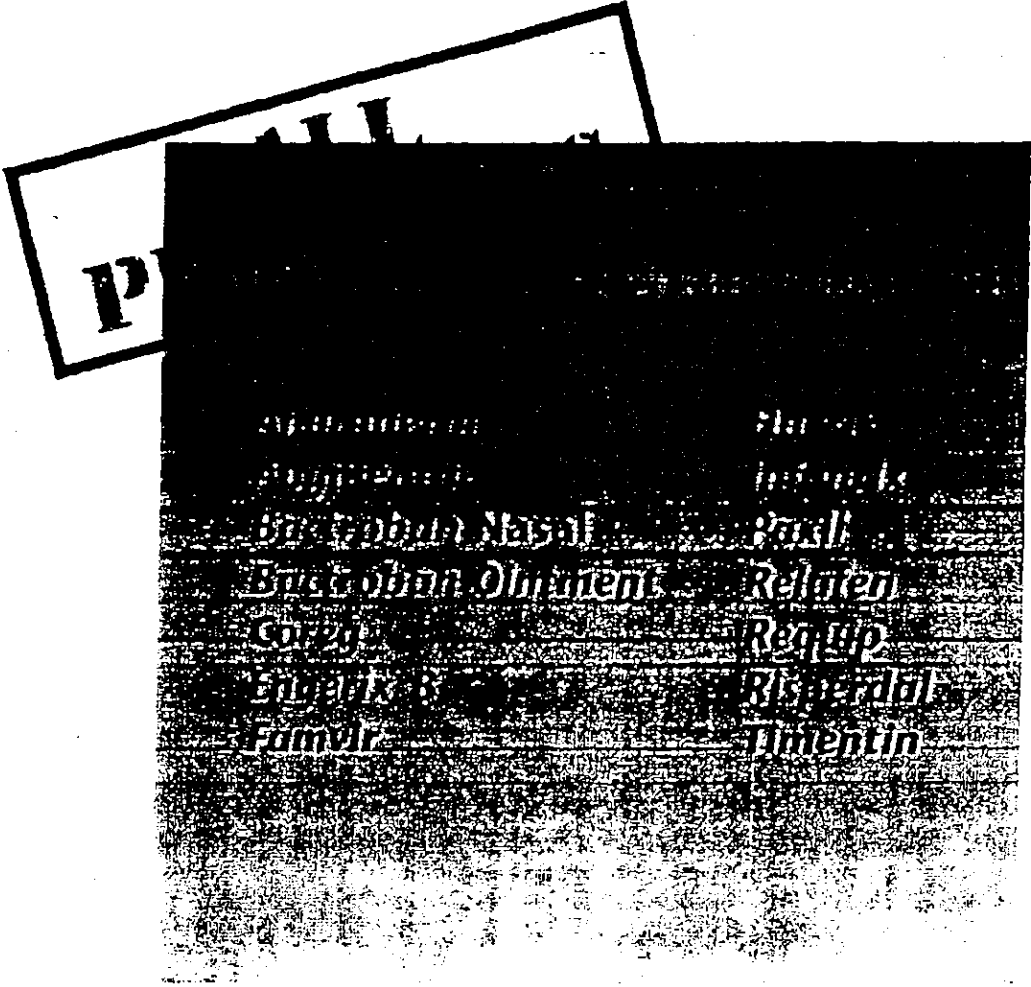


# BUSINESS PLAN GUIDE

A marketing/sales guide to help you tailor your territory business plan



Contains - Office, hospital, managed care, retail and hospital pharmacy information for all promoted products. Products are in alphabetical order

**SB** SmithKline Beecham  
Pharmaceuticals

WB 114369

## Addressing the Issue

The following information may be helpful—

When addressing this issue, utilize the new discontinuation flashcard with insert (PX5837) and convey the following points:

Minimize concerns surrounding discontinuation symptoms...

- ◆ Universal - Discontinuation symptoms occur with all psychoactive drugs including Prozac
- ◆ Infrequent - Paxil symptoms, if they occur, are generally mild and transient.
- ◆ Onset- Onset is consistent with half-life; a longer half-life merely implies the symptoms will be delayed.
- ◆ Self limiting - Paxil symptoms, if they occur, generally resolve within three to 14 days without intervention.
- ◆ Manageable - Discontinuation symptoms can be managed through gradual tapering.

Maximize benefits of optimal 24-hour half-life:

- ◆ Rapid achievement of steady state - 10 days for Paxil versus 21-50 days for Prozac
- ◆ Rapid washout - 10 days for Paxil versus 20-80 days for Prozac
- ◆ Allows for rapid washout in the case of:
  - Onset of adverse events
  - Switching to another serotonergic agent such as *Imitrex* and MAOIs
  - Switching to TCAs
  - Pregnancy
  - Allergic reaction
- ◆ Minimize concerns associated with longer half-life drugs:
  - An extended half-life drug assures that the active drug will remain in the body for weeks, even after dosing stopped.
  - With Prozac, drug inhibition can persist even after parent drug concentrations have returned to zero.

WB 114423

#### Issue #5 I won't use *Paxil* because it causes too much weight gain (or loss)

- Depression may have an effect on eating behavior. Weight loss (loss of appetite) is a somatic complaint associated with depression (Montano). However, some patients who are depressed may experience weight gain (compulsive eating or overeating).
- *Paxil* is considered weight neutral. Weight gain was not reported during the clinical trials. On average, patients in controlled trials had minimal (about one pound) weight loss versus smaller changes on placebo and active control.
- Emphasize the importance of establishing a baseline weight and then monitoring patients' weight once on *Paxil* therapy. As patients begin to feel better (less depressed), weight changes may occur, probably due to a return to their normal eating behavior.

#### Issue #6 I won't use *Paxil* because of the withdrawal symptoms associated with it

- Discontinuation symptoms are an infrequent side effect associated with all SSRIs, including *Prozac* (*Paxil* incidence rate = 2 in 1,000 patients or 0.2%). The Drug Surveillance Research Unit in the U.K. conducted a Prescription Event Monitoring study (n=13,741) and concluded all of the SSRIs exhibit similar rates of discontinuation symptoms.
- Discontinuation symptoms are generally mild and may include nausea, headache, dizziness, sleep disturbances and irritability. Discontinuation symptoms tend to be transient.
- Lilly has raised this issue to disguise the disadvantages of a long half-life. The long half-life of *Prozac* reduces physician control and can:
  - Increase exposure time to the fetus during pregnancy.
  - Lead to sustained duration of adverse events.
  - Increase drug accumulation over time.
  - Increase time to establish steady-state.
  - Limit use of drug holiday as a means of managing sexual dysfunction (see Rothschild reprint).
- The APA has recommended that all SSRIs be titrated down when discontinuing therapy.
- Use Discontinuation flashcard (PXS837)

#### Issue #7 *Paxil* takes too long to work for panic as compared to *Xanax*

- Although *Paxil* does not work as quickly as *Xanax*, a reduction in panic attacks was seen with *Paxil* during the first two-week period. Remember, panic disorder is a chronic condition requiring chronic therapy and that is where *Paxil* offers advantages: *Paxil* is the only agent that is approved for long-term use, *Paxil* effectively treats the co-morbid depression, and *Paxil* has convenient once-daily dosing.
- If the patient is extremely problematic, you can safely combine *Paxil* and *Xanax* since *Paxil* does not significantly inhibit the P<sub>450</sub> 3A<sub>4</sub> isoenzyme. However, do so for intermittent therapy so as to avoid dependence to the *Xanax*.

### *Paxil* Key Points and Tools

#### Differentiation From Other Antidepressants

- *Paxil*, the first SSRI to receive the panic disorder indication, is the gold standard for treatment of panic disorder.
- Only *Paxil* offers a 40 mg dose, providing price relief for patients on high-dose SSRIs
- *Paxil* has a well-documented cardiac safety profile and has not been shown to affect heart rate variability.
- *Paxil* has documented outstanding safety in the elderly, including patients 75 years of age or older.
- *Paxil* offers the narrowest spectrum of P450 inhibition (only IID6)
- Only *Paxil* offers a Compliance Program that respects doctor-patient confidentiality
- *Paxil* offers patient screening tools for depression, OCD and panic disorder.

#### Efficacy

- *Paxil* offers established efficacy in depression and anxiety-spectrum disorders, providing "broad-spectrum" efficacy and the "single-agent solution to the problem of multi-symptom overlap."\*\*\*

\*\* This product positioning statement should be used with primary care physicians. When speaking with a psychiatrist, focus on the high incidence of comorbidity with anxiety disorders and, because only *Paxil* is indicated for depression, OCD, and panic disorder, it is the best solution.

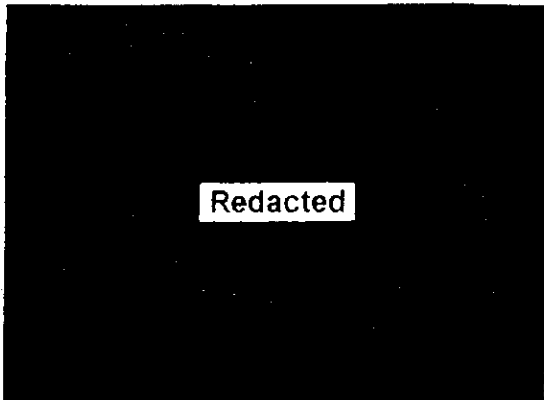
#### Safety

- *Paxil* has a well-documented cardiac safety profile and has not shown to affect heart rate or heart rate variability.
- *Paxil* has proven safety in the elderly, including individuals over 75 years of age.
- *Paxil* has a narrow range of drug interactions. *Paxil* inhibits the P4502D6 isoenzyme (as do *Prozac* and *Zoloft*), but has minimal inhibition of 2C9 or 3A4, which is responsible for metabolism of many commonly used drugs, such as *Seldane*, *Hismanal* and benzodiazepines.
- Only *Paxil* has been proven safe and effective in long-term trials for depression, OCD, and panic.

#### Cost Effectiveness

- Only *Paxil* offers a 40 mg dose, providing price relief for patients on high-dose SSRI's.
- *Paxil* offers a low average daily dose for depression, resulting in cost-effective treatment.

WB 114875



Redacted

**PAXIL**

**The Pollack Letter—an effective tool for addressing discontinuation**

This letter to the editor authored by Bruce Pollack, M.D. in the *Journal of Clinical Psychiatry*, October, 1998 is a great resource for addressing the issue of discontinuation. Dr. Pollack clarifies that discontinuation symptoms have been reported to occur with all SSRIs with onset and duration mediated by drug half-life. Most importantly, he balances the risk/benefit of a short vs. long half-life, noting the control offered by shorter half-life agents (refer to the summary memo in your November 11, 1998 field mail). You may order reprints of the Pollack Letter electronically. (PX9688).

**Gearing up for the launch of Social Anxiety Disorder**

The launch of Social Anxiety Disorder is quickly approaching and preparations are underway. FDA approval is expected sometime between April and May. Here is a preview of what you can expect over the next few months:

- Newsletter in your field mail booklet starting March 17 with information on Social Anxiety Disorder and the latest updates regarding launch.
- Training materials – will be sent to you by March 3.
- Testing for SKF, Priority, and Penn Labs on March 19-22.

It is important that we prepare ourselves to take full advantage of the opportunity Social Anxiety Disorder provides to differentiate *Paxil*, grow our market share and achieve our super bonus goal of passing *Zoloft* and attaining \$1.5 billion in sales. Let's get psyched!

**In your field mail...**

**Weight Gain-Facts Flashcard**

This piece should be added to the pocket of the new *Paxil* Brief Sales Aid received in the January field mail. Use it only if the issue is raised by a physician. Emphasize that weight gain is a potential class effect of SSRIs/SNRIs and there are effective strategies to manage it. Remember to transition to *Paxil*'s benefits: the only SSRI that provides proven short and long-term efficacy in depression, panic disorder and OCD with proven relief of associated anxiety symptoms. The last flashcard, "New SSRIs" is scheduled for shipment March 17. Great selling!

**In your field mail envelope...**

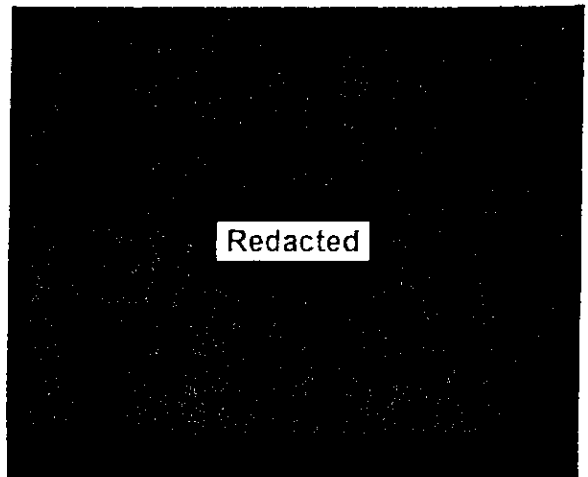
Look for the newsletter titled, "Current Approaches to Psychosis Diagnosis and Management." Please review this material thoroughly as it contains articles and interviews that will enrich and keep current your knowledge of psychoses, their diagnosis and management.



**In your field mail booklet...**

In the journal section of this booklet, a recent issue of the *Psychiatric Bulletin* presents the results of a retrospective chart review **quantifying the extent of the co-prescribing of other antipsychotics and anticholinergics with olanzapine**. This study supports current market research data as indicated in your RISPARDAL™ sales aid.

The summary and the article have been supplied for **Your Information Only**. They are not to be used in a selling situation. Do *not* duplicate or show this memo and/or article to physicians!



Redacted