

Issues Management

Company Confidential Copyright © 2001 Eli Lilly and Company

Agenda

- What is happening now?
- What have we learned?
- What are we going to do?

Company Confidential Copyright © 2001 Eli Lilly and Company

Market Place Overview Q2 (Diabetes Issue)

- Increasing scientific share of voice that supports Lilly's position on <u>diabetes</u> issue:
 - Key publications:
 - Kabinoff & Toalson's article "Metabolic issues with atypical antipsychotics in primary care: dispelling the myths" published in Primary care companion J Clin Psychiatry May 2003
 - Koller's article "Risperidone-associated diabetes mellitus: a pharmacovigilance study" published in Pharmacotherapy Jun 2003
 - TED poster in APA and Lilly safety symposium in APA
 - Independent research posters in APA:
 - Buffalo university's study,
 - syndrome X collaborative group study
 - Kato's study's poster in APA
 - Koller's poster of "Risperidone-associated diabetes mellitus" and "Quetiapine-associated diabetes mellitus"

We have learned from market research in the U.S. that it is absolutely CRITICAL that external independent parties support our position on the diabetes issue

Company Confidential Copyright © 2001 Eli Lilly and Company

Market Place Overview Q2 (Diabetes Issue)

- Other independent entities are beginning to echo our position
 - Japan
 - MHLW <u>has asked Janssen</u> to conduct a PMS study to check the incidence of hyperglycemia/diabetes in patients using Risperdal. (This study is on-going, number of patients in unknown).
 - Also, MHLW has asked Otsuka to review all of their clinical trial data and report back the incidence of hyperglycemia/diabetes in these trials. They are currently doing this analysis.
 - Canada
 - HYPERGLYCEMIA CLASS STATEMENT: All the atypical antipsychotic manufacturers have been requested to update their labels to include the hyperglycemia class statement
 - U.S.
 - ADA advisory panel meets on November 17th
 - U.S. has asked for additional funds to support an APA endocrine advisory panel

Company Confidential
Copyright © 2001 Eli Lilly and Company

Market Place Overview Q2 (Metabolic Issue)

- Continuous intensified competitors attacks zyprexa on <u>metabolic</u> issue
 - Zyprexa associated most weight gain
 - Weight gain poses serious health burden
 - Diabetes
 - Metabolic syndrome
 - Cardiovascular disease
 - Zyprexa associated highest rate of diabetes
- Key competitors activities:
 - Janssen, AstraZeneca, BMS and Pfizer's symposium attacking Zyprexa on metabolic issue in APA
 - BMS 5 posters, Pfizer 2 posters and Janssen 1 poster attaching Zyprexa on metabolic issue in APA
 - Pfizer CME on Medscape "New insights in diabetes and psychiatric illness:integrating management"
 - Pfizer "Metabolic Matter" program Jun 2003
 - Janssen's CME on DLN "Update on the metabolic effects of atypical antipsychotics" (Jonathan M. Meyer Apr 2003)
 - BMS's CME on DLN "Using Mechanism of Action to Find the Glass Slipper Fit of Treatment for the Patient" (Stephen M. Stahl, Apr 2003)

Company Confidential Copyright © 2001 Eli Lilly and Company

How customers view the metabolic issues

- Weight gain and diabetes are still the top issues. Dyslipidemia is lower on radar screen (Lipid APA research) at this time....
 - Psych advisory board (7/26/2003) indicated Pfizer reps recently suggesting cardiovascular issues with Zyprexa in their details.
- From global competitive/issue tracker (9 affiliates, started from US Oct 2002 and ended in Canada May 2003)
 - Weight gain is the highest concern of side effect in US, Canada, Germany, Australia
 - EPS is the highest concern of side effect in Japan, UK, Italy and Australia
 - Unlike Psychs, EPS is the greatest level of concern with PCPs
 - Due to concerns about weight gain and fear of diabetes, an increasing number of physicians are either avoiding Zyprexa in the acute phase or switching longer term in the U.S. and elsewhere
- Market research key learning: U.S.
 - Physician perception of weight gain and increased risk of diabetes are inextricably linked, which makes diabetes more of an issue for Zyprexa than other brands
 - Physicians believe the real problem is weight gain and that it is Zyprexa's issue as its key liability
 - Physician perceive that if you can address weight gain you will reduce the risk of diabetes.
 They are looking for tools to address weight gain that will enable them to continue to use
 Zyprexa due to its efficacy

Company Confidential Copyright © 2001 Eli Lilly and Company

Problem Statement: United States

We have learned that diabetes and weight gain are inextricably linked!

As a result of concerns about weight gain and fear of diabetes, an increasing number of physicians are either avoiding Zyprexa in the acute phase or switching longer term. These actions are depriving patients of the benefits of Zyprexa.

We expect that a similar change may occur in Europe with the launch of Abilify/Geodon in 2004.

Company Confidential Copyright © 2001 Eli Lilly and Company

Draft: For business planning purposes only

Situational Analysis: Where we were vs. Where we are going

From:

- Weight gain is manageable
- Weight gain is predictable
- Weight gain is not the only predictor of diabetes
- Diabetes risk is a class
 effect with comparable rates
 across all products
- Diabetes is mainly a patient population issue
- Handling diabetes and weight gain as an objection

To

- Lilly understands the challenges physicians face in treating this population
- Lilly acknowledges weight gain challenges and potential consequences.
- Lilly is providing me with options to address weight gain in some of my patients
- External entities provide me with the facts related to diabetes
- Lilly is providing help regarding how to to assess, counsel, and refer patients at risk for diabetes

Result: A fundamental change in the way we interact with customers!

Company Confidential Copyright © 2001 Eli Lilly and Company

File name location
9/1/2004 8
Draft: For business planning purposes only

"Belief Statements" desired belief in customers mind 18 months from now

- I sense a change in Lilly's tone and approach they have demonstrated that they understand the weight gain challenges I face when I choose Zyprexa. They now acknowledge that weight gain is very difficult to manage and can have potentially serious consequences.
- 2. That said, Lilly is providing me with options that help me address weight gain in some of my patients and enable me to keep those patients on Zyprexa longer. This enables me to focus on treating the core psychiatric illness with the medication I deem most appropriate.
- 3. I believe that diabetes is pervasive in my patients with severe mental illness. I am increasingly convinced that it has little, if anything, to do with which medication I choose. However, I am confident that I can assess, counsel, and refer patients at risk for diabetes.
- 4. I now feel more confident addressing the challenges my patients face, and can depend on Zyprexa to help me help my patients.

Company Confidential Copyright © 2001 Eli Lilly and Company File name location 9/1/2004 9

Draft: For business planning purposes only

Q3 2003 Communications

Customers sense a change in tone and approach by Oct 31st

Operation Restore Confidence Kick Off

DTP Satellite Dinner Programs?

Based on Buy-Up Approval!

Retrospective Mgd Care Data Analysis

SFW Mailing to every MD & Tx Team Member

Significant Kick-Off Event

Direct Mail – Weight Mgmt

Quantitative Market Research

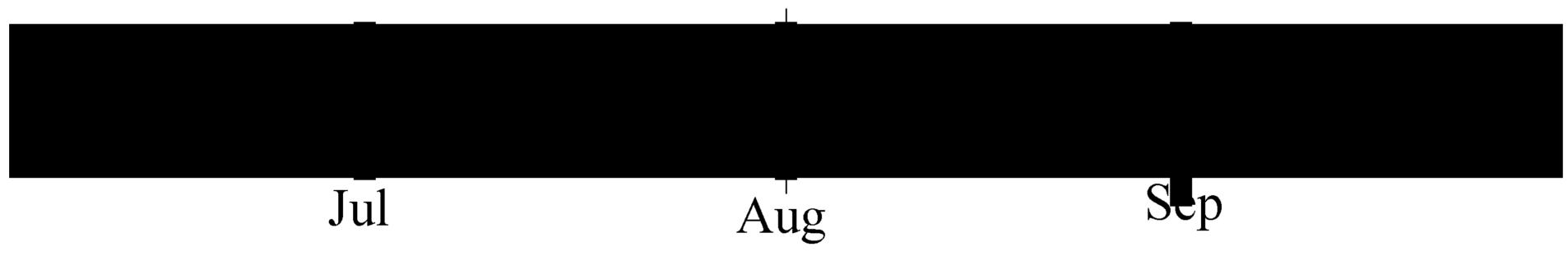
SFW Journal Ads Issues Motivational Campaign

Buse CME Extension Treatment Team Mailing List

Sales Force Training-New tone

Gupta CD-ROM Weight Management Telesessions-

Wellness Success Story Development



Company Confidential Copyright © 2001 Eli Lilly and Company

Draft: For business planning purposes only

Q4 2003 Communications

Pharmacy Rx Reminders & Wellness Direct Mail Diabetes Sales Force Training CD-ROM Development — Wellness Patient Starter Kit Development -Zyprexa Direct Campaign — SFW Journal Ads SFW Group Program Expansion SFW Physician Experience Trail Diabetes Reprint #2 SFW Menu/Exercise Expansion SFW Promo Internet Expansion SFW Payor Pilot -Oct Nov Based on Buy-Up Approval!

Draft: For business planning purposes only

Zyprexa MDL 1596: Confidential-Subject to Protective Order

File name location

9/1/2004 11

Company Confidential

Copyright © 2001 Eli Lilly and Company

Issues Management Strategic Focus

New Approach Summary: United States

- Updated customer belief statements that are more realistic and in line with our long term objectives for the brand
- Change in tone from "indignant" to "empathy with conviction"
- Discuss weight gain "up front", integrated within the context of the brand promise. We will no longer address weight gain as an objection.
- Major focus on providing services and solutions that may help with some patients (will NOT be the answer for everyone)
- Significant proposal for funding to "shock the market"
 - Including ongoing investment beginning Q3, 2003 and through 2004

Company Confidential
Copyright © 2001 Eli Lilly and Company