

3<sup>rd</sup>  
UNITED STATES  
*Schizophrenia*  
ADVISORY  
BOARD  
MEETING

*December 10, 1995  
Caribe Hilton  
San Juan, Puerto Rico*



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## Faculty

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## Core Project Team Members

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**JOHN R. RICHARDS, RPH**

Manager, Zyprex - Marketing Plans

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Clinical Research Physician

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Lilly Research Laboratories

**PIERRE TRAN, MD**

Clinical Research Physician

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# Eli Lilly and Company

SUNDAY, DECEMBER 10, 1995

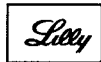
CARIBE HILTON

SAN JUAN, PUERTO RICO

## Agenda

- |               |  |
|---------------|--|
| 12:00-1:00 PM | <b>BUFFET LUNCH</b>  |
| 1:00-2:00     | <b>HGAJ DATA PRESENTATION</b><br><i>Charles Beasley, Jr, MD</i>  |
| 2:00-2:30     | <b>GROUP DISCUSSION</b>  |
| 2:30-3:00     | <b>OVERVIEW OF THE INTEGRATED OLANZAPINE DATABASE</b><br><i>Gary D. Tollefson, MD, PhD</i>   |
| 3:00-3:15     | <b>COFFEE BREAK</b>  |
| 3:15-4:30     | <b>ADVISORY COMMITTEE DISCUSSION</b><br><i>Gary D. Tollefson, MD, PhD; Todd Sanger, PhD; Charles Beasley, Jr, MD; Pierre Tran, MD; Winston Satterlee, MD</i> |
| 4:30-4:45     | <b>OLANZAPINE LABEL</b><br><i>Jim Lancaster</i>  |
| 4:45-5:15     | <b>GROUP DISCUSSION</b><br><i>Jim Lancaster; John R. Richards, RPh</i>   |
| 5:15-5:30     | <b>OVERVIEW OF THE 1996 CLINICAL PLAN</b><br><i>Gary D. Tollefson, MD, PhD</i>   |
| 5:30-6:00     | <b>GROUP DISCUSSION</b><br><i>Gary D. Tollefson, MD, PhD; Charles Beasley, Jr, MD</i>  |
| 6:00-6:15     | <b>CLOSING REMARKS</b>   |
| 6:15-8:00     | <b>RECEPTION/LIGHT DINNER</b>  |

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PLEASE RETURN TO: JOHN R RICHARDS MC639 73/02

February 4, 1994 13:43

To: HADLEY GARY R IVM1  
RICHARDS JOHN R IVM1  
cc: DICKSON DENISE L IVM1  
JONES YVONNE N IVM1  
PERSUY JACQUELINE IVM1

Re: Off Label Studies in Olanzapine Life Plan

I just wanted to drop you two a note to ask you to seriously consider adding some off label studies into Life Plan. We all know that the off label segment is large, particularly in some countries. Also, we know from our work that there are some common off label uses across all countries -- agitation and anxiety probably at the top of the list, but there are several important ones.

Redacted

Jacqueline Persuy and I discussed this on her recent visit. She believes these off label studies are essential to Olanzapines' success in France and obviously is very interested in getting them into our time line as soon as possible.

I would appreciate your feedback on this issue.

Regards,

Denise L. Dickson

DICKSON DENISE L

IVM1

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## HGAJ Study Report Documentation - Individual Marked Lab Abnormalities

Description: This binder contains output used to write the individual marked lab abnormalities section of the CRS (acute and double-blind extension) and also the one-page patient summaries for patients with abnormal labs in the open-label extension.

The following identifies which output was used for the corresponding CRS or OPPS:

Purple tab - Output 22 June 1995 was used for the acute study report and was run off the DBOLXI database. This output identifies all patients with 2 consecutive abnormal labs and/or abnormal at endpoint. Abnormals at endpoint does include patients who were abnormal at visit 8 and continued into the double-blind extension. This criteria is slightly different from the other CSR's.

Blue tab - Output 1 June 1995 was used for the double-blind extension report.

Red tab - Output 14 May 1995 was used for the first acute report. This report was run off the acute database. However, this acute report was never finished due to the update of database that impacted the acute report.

2 purple tabs - Output 05 July 1995 was used for the OPPS for patients in the open-label extension phase.

John Krueger

ZY 1234

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