# Zypexa Labeling Status

- **Major Points**
  - Dose and Administration
    - FDA: Dose titration; start everyone at 5 mg
    - Now: 5 - 10 mg starting dose
  - Liver Monitoring
    - FDA: Useful to obtain baseline & monthly x3: all patients
    - Now: Only in patients with significant liver disease
  - Tardive Dyskinesia
    - FDA: Class labeling
    - Now: Commit to external review panel - future potential

# Zypexa Labeling Status

- **Major Points**
  - Prolactin Elevation
    - FDA: Persistent elevation during chronic administration
    - Now: Down-graded to "modest" persistence
  - Body Weight
    - FDA: Weight gain as "Precaution"
    - Now: Moved to "Adverse reactions" & greater effect at low body weight
  - Haloperidol comparative data
    - FDA: Comparative data not allowed
    - Now: Status quo: Consistent for all manufacturers

# Zypexa Labeling Status

- **Next Regulatory Steps**
  - Review of Safety Update and Literature Search
  - Approval of Final Labeling by FDA Sr. Management
  - DDMAC Review of Promotional Material

STATE OF CONNECTICUT
DEPARTMENT OF MENTAL HEALTH AND ADDICTION SERVICES
GREATER BRIDGEPORT COMMUNITY MENTAL HEALTH CENTER

DMHAS
Department of Mental Health and Addiction Services

12-3

Nov 20, 1997

Dear Dr Tolfson:

Thank you for sending me the Zyprexa slide kit for use in lecturing and teaching. I understand a new kit will be shortly available with more complete information. Kindly send me a set of the new slides as soon as possible. A local Lilly rep has asked me to do several presentations, and I would like to make the best and closest effort.

Thank you!

cordially
Kathleen Degan, M.D.

Send a note to me.

Post-it® Fax Note 7671 | Date 11/20 | # of pages ▶ 1
To Dr Greg Tolfson | From K. Degan MD
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