• **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
Zyprexa 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
Zydeco 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
November 20, 1997

Dear Dr. Tolifson:

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 clearest effort.

Thank you,

Cordially,

Kathleen Repa, M.D.

1635 Central Avenue • P.O. Box 5117
Bridgeport, Connecticut 06610
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