

COMPETITIVE INFORMATION

APA SUBCOMMITTEE ON METABOLIC ISSUES

Source—Dr. John Newcomer from an interview conducted by a vendor.

- The Metabolic Issues subcommittee at APA will be mostly a “business meeting” group.
 - “Nobody will be dropping bombshells.”
- For the most part, there are few dissenting opinions about what the APA must do. This is because it’s based on as much clear science as possible, more about patient safety than drugs, and because it doesn’t slam any one drug.
 - “It will be a ‘tightening of the screws’ on the issue of the adverse effects of weight gain as caused by use of atypicals, but nothing major.”
- APA guidelines, like ADA, will not state clearly that all drugs are the same, though they will point out that efficacy is in large part similar.
 - “Zyprexa is still a great drug. Many practitioners will continue to use it because of easy dosing, sure results, and the usefulness of sedation. Its ease of use is very attractive the PCP market. This weight gain issue simply must be addressed, though.”
- The continued focus of the APA committee work will be the most rigorous science. As such, registration trials for all of the atypical antipsychotics proved weight gain, which is the real health issue.
 - “Any treatment algorithms suggested by APA will simply point out what we already know about weight gain. They must also measure initial risk factors when treatment begins. There will be discussion of medical comorbidity. “
- The subcommittee will discuss the issue of “informed consent,” similar but not exactly like the black box warning in Japan.
- Months ago, APA refused to sign on to ADA work until it saw a draft. APA felt that if the ADA pronouncements were politically explosive, it would upset the APA sponsors, providing an unfair advantage in the market.
- Including John Newcomer and John Kane, there will be a large number of academics and practitioners on the APA subcommittee. The total list has not yet be determined.

- The APA went to pains to make sure all wanted to participate could be on the committee. The subcommittee is sensitive to the impression that this could be politically charged, and want to avoid accusations of cherry picking the members for an opinion in any one direction.
 - “CINP in Paris will have much more interesting information that the APA in New York. There, Herb Melzer will be presenting more defined treatment algorithm from the International Psychopharmacological Algorithm Project.”

PFIZER – GEODON

Source— Fletcher Physician Network

- Geodon reps are currently counterdetailing Zyprexa based on the findings of the American Diabetes Association.
- Reps are distributing “Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes,” from *Diabetes Care*, February 2004 to PCP doctors
- Pfizer is distributing “home baked bread” in the forms of a press release, dated February 20, 2004, that lists warnings about Zyprexa that have appeared in the press
 - Points brought up in the release:
 - Eli Lilly “Dear Doctor” letter that warns of significantly higher risk of stroke and death in elderly patients
 - In five placebo-controlled trials, 3.5% of elderly patients taking Zyprexa died of all causes, compared with 1.5% taking placebo
 - J&J issued a similar warning for Risperdal
- Other home baked bread is a homemade Excel spreadsheet entitled “Geodon Challenge” which tracks target dose and patient outcome.