

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE
WITH THE PEDIATRIC SUBCOMMITTEE
OF THE ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE

Monday, February 2, 2004

8:00 a.m.

Holiday Inn Bethesda
Versailles I and II
8120 Wisconsin Avenue
Bethesda, Maryland

PARTICIPANTS

1 looking at changed scores on a handful of a
2 priori-defined symptoms from the rating scales
3 would be very helpful.

4 DR. GOODMAN: Along those lines, as I
5 mentioned earlier, the Hamilton has an item on
6 agitation, the CDRS has an item on irritability, so
7 that could be a first quick look, and you wouldn't
8 have to look at treatment emergent, you can look at
9 rating scale items.

10 I agree that one needs to give careful
11 thought into what symptoms or how we are describing
12 this constellation of symptoms, because it could be
13 very problematic..

14 For one reason, a number of symptoms you
15 would expect to get better with the SSRIs, and what
16 we are really looking for is a minority of patients
17 in whom you see a paradoxical increase in those
18 symptoms.

19 So, I think we need to take a very careful
20 approach to this analysis.

21 DR. RUDORFER: We have four more questions
22 on this topic.

23 I am sorry. Dr. Laughren.

24 DR. LAUGHREN: Just one follow up on a
25 suggestion that has come up from several committee

1 members now about looking at items from the rating
2 scales. That was actually done here, and it turned
3 out not to be very helpful.

4 Now, this was a similar analysis that had
5 been done with the adult data years ago, for
6 example, looking at patients who move from looking
7 at the suicide item on the HAM-D and looking at
8 patients who move from zero to 1 to a 3 or 4.

9 That did not detect a signal in these
10 trials, and part of the problem may have been that
11 these events often did not occur at a time when the
12 HAM-D would be done, because the HAM-D is done at
13 regular intervals.

14 If the event occurs between visits, which
15 it almost always does, and then the patient is
16 discontinued at that point, you never get a HAM-D
17 or whatever other instrument is being used.

18 So, companies did try that approach, and
19 it was not particularly productive.

20 DR. RUDORFER: We are now going to turn to
21 Drs. Malone, McGough, Pfeffer, and Ortiz, and then
22 move on to Question 2 more specifically.

23 DR. MALONE: I am sorry, I just stepped
24 out, so I may have missed things that were just
25 discussed, but I was thinking that looking at