Minutes: October 8, 1999

Psychopharmacological Drugs Advisory Committee

Issue : NDA 19-839 (S), Zoloft® (sertraline hydrocholoride) Pfizer

The meeting was held at the Holiday Inn in Bethesda, Maryland. Prior to the meeting, the members, consultants and guests had reviewed background material from the FDA and from Pfizer. There were approximately 150 persons in attendance.

Attendance:
PDAC Members Present: Carol Tamminga, M.D., Roberto Dominguez, M.D., Barbara Geller, M.D., Edwin Cook, M.D., Andrew Winokur, M.D., Ph.D.,Robert Hamer, Ph.D.

PDAC Members Absent: Gaurdia Banister, Ph.D., Abby Fyer, M.D

PDAC Consultant: Ella Lacey, Ph.D.

PDAC Guest: Timothy Brewerton, M.D., Steven Southwick, M.D., and Carol North, M.D.

FDA Participants: Robert Temple, M.D., Russell Katz, M.D, Thomas Laughren, M.D., David Smith, Ph.D., Earl Hearst, M.D.

Overview of Pfizer's Presentation:

Gary Ryan Ph.D., Pfizer Clinical Group Director, gave the introductory and concluding comments. Charles Marmar M.D., University of California, V.A. Medical Center, S.F. presented an overview of PTSD. Gail Farfel, Ph.D., Sr. Associate Director, discussed the findings on the efficacy and safety of the PTSD clinical data.

Overview of FDA's Presentation:

Thomas Laughren, M.D., gave an overview of the FDA issues. David Smith, Ph.D., presented the statistical review.

Open Public Hearing:

Three members from the public presented statements which represented the views of the Sidran Foundation, the Anxiety Disorders Association of America and the International Society for Traumatic Stress Studies.

Following a discussion dealing with general issues regarding PTSD research and specifically about this NDA the committee voted on the following questions:

QUESTIONS REQUIRING A VOTE OF THE PDAC:

1. Has the sponsor provided evidence from more than one adequate and well controlled clinical investigation that supports the conclusion that Zoloft is effective for the treatment of posttraumatic stress disorder (PTSD)?

Yes = 6 **No = 1**

2. Has the sponsor provided evidence that Zoloft is safe when used in the treatment of PTSD?

Yes = 7 **No = 0**

Regarding gender differences, Dr. Hamer's caveat reflected the consensus of the committee. He stated that, although the sponsor has failed to show an effect of Zoloft on PTSD in males, that is entirely different than saying that Zoloft has been shown to be not effective in males. Hence the committee thought the gender issue could be handled by describing the results of the studies in the labeling.

Regarding the relationship of PTSD with depression, the consensus of the committee was that PTSD is a separate entity and that Zoloft has been shown to have a PTSD effect independent of its antidepressant effect.

A verbatim transcript of this meeting will be available on the FDA's Dockets Management Branch Website approximately 30 days after the meeting. The address is HTTP://www.fda.gov/ohrms/dockets/ac/acmenu.htm.

I certify that I attended the October 8, 1999 meeting of the Psychopharmacologic Drugs Advisory Committee and that these minutes accurately reflect what transpired.

Sandra Titus 10/20/99

Sandra Titus, Ph.D. Date
Executive Secretary, PDAC

Carol Tamminga Oct 20, 1999

Carol Tamminga, M.D. Date
Chair, PDAC