

# **APPENDIX**

## **6**



National Institute of Diabetes and  
Digestive and Kidney Diseases  
Bethesda, Maryland 20892

Statement from the External Advisory Committee  
Medical Therapy of Prostatic Symptoms (MTOps) Trial  
Concerning ALLHAT Report on Effect of Alpha-Blocker on Cardiovascular Disease Events  
Telephone Conference Call of April 25, 2000

External Advisory Committee: Drs. Barry, Cockett, Roberts, Williford and Rous

MTOps Investigators: Dr. McConnell (Steering and Planning Committee), Dr. Bautista (Biostatistical Coordinating Center), and Pamela Burrows, M.S. (Biostatistical Coordinating Center)

National Institutes of Health: Drs. Nyberg and Kusek

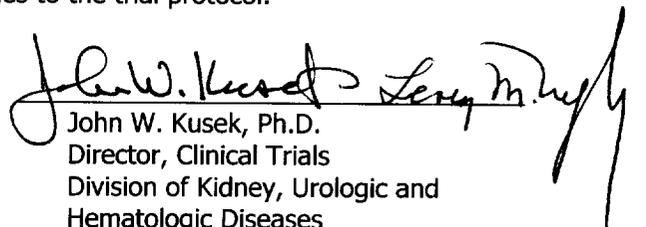
A conference call was held on April 25, 2000 to discuss the analyses provided by the Biostatistical Coordinating Center in response to a prior conference call of the External Advisory Committee on March 22, 2000. The purpose of these calls was to review data from the MTOps trial on cardiovascular disease endpoints in response to the report from the Antihypertensive and Lipid-lowering Treatment to Prevent Heart Attack Trial (ALLHAT) showing that compared with doxazosin, chlorothalidone significantly reduces the risk of combined cardiovascular disease events, particularly congestive heart failure, in high-risk hypertensive patients (Journal of the American Medical Association 283:1967-1975, 2000).

The External Advisory Committee made the following statements after reviewing two data packets provided by the Biostatistical Coordinating Center on this matter.

The External Advisory Committee has carefully reviewed the data on the incidence of congestive heart failure requiring or not requiring hospitalization and finds that:

- There is a low absolute risk of congestive heart failure across the trial.
- There is no significant difference in the incidence rates of congestive heart failure among the various treatment arms. It was recognized, however, that because of the small number of events the confidence intervals around these rates were quite large.
- Because the confidence intervals around the rates of congestive heart failure are large, the Committee could not rule out that there may in fact be a true difference in the incidence rates of congestive heart failure among the treatment arms in the MTOps Trial.
- Based on their review of the data, the External Advisory Committee did not recommend changes to the trial protocol.

Prepared by:



John W. Kusek, Ph.D.  
Director, Clinical Trials  
Division of Kidney, Urologic and  
Hematologic Diseases  
National Institutes of Health  
Bethesda, Maryland 20892  
(301) 594-7735  
and Leroy M. Nyberg, Ph.D., M.D., Director, Urology Programs

Date: May 24, 2000