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FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH

ANTIVIRAL DRUGS ADVISORY COMMITTEE

8:30 a.m.

Thursday, July 29, 1999

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Whetstone Room
Gaithersburg Holiday Inn
Montgomery Village Avenue
Gaithersburg, Maryland

ATTENDEES

COMMITTEE MEMBERS:

SCOTT M. HAMMER, M.D., Chairman Chief, Division of Infectious Disease Columbia Presbyterian Medical Center 630 West 168th Street New York, New York 10032

RHONDA W. STOVER, R.PH., Executive Secretary Advisors and Consultants Staff Food and Drug Administration, HFD-021 5600 Fishers Lane Rockville, Maryland 20857

PAMELA S. DIAZ, M.D. Medical Director of Communicable Diseases Chicago Department of Health 2160 West Ogden Avenue Chicago, Illinois 60612

HENRY MASUR, M.D. Chief, Critical Care Medicine National Institutes of Health Critical Care Medicine Department Building 10, Room 7D43 10 Center Drive, MSC-1662 Bethesda, Maryland 20892

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College of Medicine
Department of Preventative Medicine
and Environmental Health
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Iowa City, Iowa 52242

BRIAN WONG, M.D. Chief, Infectious Diseases Infectious Diseases Section VA Connecticut Health Care System 950 Campbell Avenue (111-I) West Haven, Connecticut 06516

ATTENDEES (Continued)

COMMITTEE MEMBERS: (Continued)

RAM YOGEV, M.D.
Director, Section of Pediatric &
 Maternal HIV Infection
Children's Memorial Hospital
2300 Children's Plaza, #155
Chicago, Illinois 60614

SGE CONSULTANTS:

P. JOAN CHESNEY, M.D.
Professor of Pediatrics
Department of Pediatrics
University of Tennessee College of Medicine
50 North Dunlap
Memphis, Tennessee 38103

ROY GULICK, M.D.
Assistant Professor of Medicine
Cornell University Medical Center
The Cornell Clinical Trials Unit
525 East 68th Street, F2400, Box 566
New York, New York 10021

PRINCY KUMAR, M.D. Georgetown University Medical Center Kober-Cogan Building, Suite 110 3800 Reservoir Road, N.W. Washington, D.C. 20007

WM. CHRISTOPHER MATHEWS, M.D., M.S.P.H. Director, Owen Clinic & AIDS Service Professor of Clinical Medicine University of California at San Diego Medical Center 200 West Arbor Drive San Diego, California 92103

PETER ROTHSTEIN, M.D. Columbia Presbyterian Medical Center Babies and Children's Hospital 622 West 168th Street, BN 440 New York, New York 10032

ATTENDEES (Continued)

SGE CONSULTANTS: (Continued)

MEHERNOOR F. WATCHA, M.D.
Associate Professor
Department of Anesthesiology and
Critical Care Medicine
Children's Hospital of Philadelphia
34th Street and Civic Center Boulevard
Philadelphia, Pennsylvania 19104

FOOD AND DRUG ADMINISTRATION STAFF:

THERESE CVETKOVICH, M.D.
RUSS FLEISCHER, PAC, M.P.H.
HEIDI JOLSON, M.D., M.P.H.
SANDRA L. KWEDER, M.D.

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1	PROCEEDINGS			
2	(8:30 a.m.)			
3	DR. HAMMER: Good morning. I'd like to welcome			
4	everyone to the beginning part of the Antiviral Products			
5	Advisory Committee meeting.			
6	This first session, if you will, is an open			
7	session by the regulations. So, I am just calling this			
8	open session to order. As part of that, I actually would			
9	just like to go around the room and have the committee			
10	members, agency representatives, and guests introduce			
11	themselves. Dr. Jolson?			
12	DR. JOLSON: I'm Heidi Jolson. I'm the			
13	Director of the Division of Antiviral Drug Products.			
14	DR. FLEISCHER: Russ Fleischer, clinical			
15	reviewer in the Division of Antiviral Drug Products.			
16	DR. DIAZ: Pamela Diaz, Chicago Department of			
17	Public Health.			
18	DR. YOGEV: Ram Yogev, Children's Memorial			
19	Hospital, Chicago.			
20	DR. WOOLSON: Robert Woolson, University of			
21	Iowa.			
22	MS. STOVER: Rhonda Stover, FDA.			
23	DR. HAMMER: Scott Hammer, Columbia.			
24	DR. MASUR: Henry Masur, Intramural Program,			
25	NIH.			

1	DR. WONG: Brian Wong, Yale University.	
2	DR. GULICK: Trip Gulick, Cornell.	
3	DR. KUMAR: Princy Kumar, Georgetown	
4	University.	
5	DR. MATHEWS: Chris Mathews, UC San Diego.	
6	DR. CHESNEY: Joan Chesney, the University of	
7	Tennessee, Memphis.	
8	DR. WATCHA: Meb Watcha, Department of	
9	Anesthesiology, Children's Hospital of Philadelphia.	
10	DR. ROTHSTEIN: Peter Rothstein, Babies and	
11	Children's Hospital, Columbia Presbyterian Medical Center.	
12	DR. HAMMER: Thank you.	
13	As part of the open session, we need to have a	
14	period for an open public hearing. So, I will just ask -	
15	there is no one signed up for this is there anyone in	
16	the audience who wishes to make a public statement?	
17	(No response.)	
18	DR. HAMMER: If not, we will close the open	
19	public session and I will move to close the open session.	
20	(Whereupon, at 8:33 a.m., the committee was	
21	recessed, to reconvene in closed session, this same day.)	
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