

CENTER FOR DRUG EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

FORTY-SEVENTH MEETING
OF THE
DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE

This transcript has not been edited or corrected, except where relevant for the deletion of materials not releasable under the Freedom of Information Act. The Food and Drug Administration makes no representation as to its accuracy.

8:37 a.m.
Friday, September 5, 1997

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

ASSOCIATED REPORTERS OF WASHINGTON

APPEARANCES

COMMITTEE MEMBERS:

JOSEPH McGUIRE, JR., M.D., Chairman
Carol Herzog Professor of Dermatology
and Pediatrics
Stanford University School of Medicine
Department of Dermatology
MSLS Building, Room P-204
Stanford, California 94305

TRACY RILEY, Executive Secretary
Advisors and Consultants Staff
Center for Drug Evaluation and Research
Food and Drug Administration
Chapman Building, Room 200
5600 Fishers Lane
Rockville, Maryland 20857

SUSAN COHEN, B.S., Consumer Representative
3814 Inglemere Drive
Bethesda, Maryland 20817

S. JAMES KILPATRICK, PH.D.
Professor of Biostatistics
Medical College of Virginia
Virginia Commonwealth University
1101 East Marshall Street
Sanger Hall, Room B-1-039-A
Richmond, Virginia 23298-0032

JOEL MINDEL, M.D.
Director, Neuro-Ophthalmology
Mt. Sinai Medical Center
Annenburg Building 22-14, Box 1183
New York, New York 10029-6574

MILTON ORKIN, M.D.
Clinical Professor
Department of Dermatology
University of Minnesota
2733 Huntington Avenue South
Minneapolis, Minnesota 55416

ASSOCIATED REPORTERS OF WASHINGTON

1522 North Carolina Avenue, N.E.

APPEARANCES (Continued)

SPECIAL GOVERNMENT EMPLOYEES, CONSULTANTS
AND GUEST SPEAKERS:

WILMA BERGFELD, M.D.
Head, Clinical Research
Department of Dermatology
Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195-5032

COLIN CRAWFORD, M.B., CH.B., MRCP, DTM&H
Neuromuscular Diseases Department
Division of Neuroscience and
Psychological Medicine
Charing Cross Hospital
Fulham Palace Road
London, United Kingdom W6 8RF

KEN HASHIMOTO, M.D.
Professor and Chair
Departments of Dermatology and
Syphilology
Wayne State University School of Medicine
4201 St. Antoine
Detroit, Michigan 48201

W. CHRISTOPHER MATHEWS, M.D., M.S.P.H.
Antiviral Drugs Advisory Committee Member
Professor of Clinical Medicine
University of California at San Diego
Medical Center
Mail Code 8681
200 West Arbor Drive
San Diego, California 92103-8681

O. FRED MILLER, III, M.D.
Geisinger Medical Center
North Academy Avenue
Danville, Pennsylvania 17822-1406

ASSOCIATED REPORTERS OF WASHINGTON

APPEARANCES (Continued)

SPECIAL GOVERNMENT EMPLOYEES, CONSULTANTS
AND GUEST SPEAKERS: (Continued)

CYNTHIA MOORE, M.D., PH.D.
Birth Defects & Genetic Disease Branch
Centers for Disease Control and
Prevention, MS-F45
Atlanta, Georgia 30333

EDWARD J. SHANNON, PH.D.
G.W. Long Hansen's Disease Center
P.O. Box 20572
Baton Rouge, Louisiana 70894

EVA SIMMONS-O'BRIEN, M.D.
Drugs Assistant Professor of
Dermatology and Internal Medicine
Johns Hopkins University School of Medicine
550 North Broadway, Suite 1002
Baltimore, Maryland 21287-0900

RANDOLPH WARREN
CEO
Thalidomide Victims Association of Canada
P.O. Box 9061 sub 40
London, Ontario
Canada N6E 1V0

FOOD AND DRUG ADMINISTRATION STAFF:

DENNIS BASHAW, PHARM.D.
Biopharmacist, Division of Pharmaceutical Evaluation III

DEBRA BIRNKRANT, M.D.
Acting Director, Division of Antiviral Drug Products

MURRAY LUMPKIN, M.D.
Deputy Center Director for Review Management, CDER

KATHRYN O'CONNELL, M.D.
Medical Reviewer

ASSOCIATED REPORTERS OF WASHINGTON

APPEARANCES (Continued)

FOOD AND DRUG ADMINISTRATION STAFF: (Continued)

BRENDA VAUGHAN, M.D.
Medical Reviewer

MICHAEL WEINTRAUB, M.D.
Director, Office of Drug Evaluation V

JONATHAN WILKIN, M.D.
Director, Division of Dermatologic and Dental Drug Products

JANET WOODCOCK, M.D.
Director, Center for Drug Evaluation and Research

CELGENE REPRESENTATIVES:

ROBERT H. GELBER, M.D.
KAREN KOOK, PH.D.
THOMAS REA, M.D.
STEVE THOMAS, PH.D.
BRUCE WILLIAMS
LEO YODER, M.D.
JERRY ZELDIS, M.D., PH.D.

ALSO PRESENT:

ALLEN MITCHELL, M.D.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.