Clinical Research and Products Liability Issues: Use of Women of Childbearing Potential in Drug Trials

Monday, October 30, 1995
New York City

Co-sponsored by the Food, Drug and Cosmetic Law Section and the Committee on Continuing Legal Education of the New York State Bar Association

Program Agenda

8:00-8:30 a.m.	REGISTRATION (outside of meeting room)
8:30-8:40	INTRODUCTION Speaker: **David S. Weinstock, Esq.**
8:40-9:40	THE FDA AND NIH GUIDELINES ON THE INCLUSION OF WOMEN AS SUBJECTS IN CLINICAL RESEARCH Speakers: **Ruth B. Merkatz, Ph.D., R.N.** **Eugene Hayunga, Ph.D.**
9:40-10:00	QUESTION AND ANSWER PERIOD
	PANEL I
10:00-11:05	RESEARCH ISSUES: INSTITUTIONAL REVIEW BOARD RESPONSIBILITIES AND ETHICAL CONCERNS OVER POTENTIAL MATERNAL AND/OR FETAL INJURY Speakers: **Ellen Berman, M.D.** **F. William Dommel, Jr., Esq.** **Alan R. Fleischman, M.D.** **Barbara F. Mishkin, Esq.**
11:05-11:25	QUESTION AND ANSWER PERIOD
11:25-11:40	COFFEE BREAK
	PANEL II
11:40-12:40 p.m.	LIABILITY ISSUES FOR PHARMACEUTICAL MANUFACTURERS, CLINICAL INVESTIGATORS AND RESEARCH INSTITUTIONS Speakers: **Steven E. Pegalis, Esq.** **Ruth Scheuer, Esq.** **Mary Weiser, R.N., J.D.** **Clinician (T.B.A.)**
12:40-1:00	QUESTION AND ANSWER PERIOD
1:00	ADJOURNMENT

Program Faculty

Overall Planning Chair

David S. Weinstock, Esq.
Senior Regulatory Counsel
Sanofi, Inc.
New York City

Speakers
(in alphabetical order)

Ellen Berman, M.D.
Associate Professor
Department of Medicine
Memorial Sloan Kettering Cancer Center
New York City

F. William Dommel, Jr., Esq.
Senior Policy Advisor
Office for Protection from Research Risks
Rockville, M.D.

Alan R. Fleischman, M.D.
Senior Vice President
New York Academy of Medicine
New York City

Eugene Hayunga, Ph.D.
Research Policy Officer
Office of Research on Women's Health
National Institutes of Health
Bethesda, M.D.

Ruth B. Merkatz, Ph.D., R.N.
Director, Office of Women's Health
Food and Drug Administration
Rockville, M.D.

Barbara F. Mishkin, Esq.
Hogan & Hartson
Washington, D.C.

Steven E. Pegalis, Esq.
Pegalis & Wachsman
Great Neck

Ruth Scheuer, Esq.,
Ackerman, Salwen, Glass,
Barnett and Ehrenfeld
New York City

David S. Weinstock, Esq.
Senior Regulatory Counsel
Sanofi, Inc.
New York City

Mary Weiser, R.N., J.D.
Office of Legal Affairs
Memorial Sloan Kettering Cancer Center
New York City