



SARS Diagnostics: Scientific and Regulatory Challenges

July 14, 2003
DoubleTree Rockville Hotel and Executive Center
Rockville, Maryland



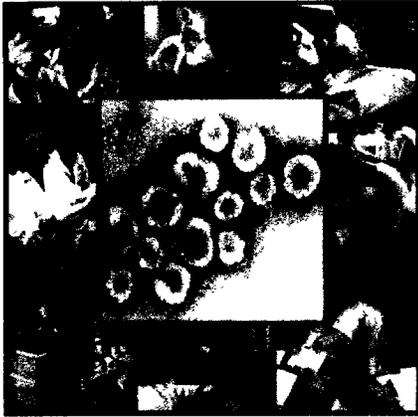
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health



2003N-0201



LST /



Program

FDA Workshop on
SARS Diagnostics:
Scientific and Regulatory Challenges
with Diagnostics for Emerging Pathogens

July 14, 2003

DoubleTree Rockville Hotel and Conference Center,
Rockville, MD

8:00 AM – 5:00 PM

7:00 – 8:00 a.m.

REGISTRATION

8:00 – 8:30 a.m.

WELCOME: David Feigal, Jr., Center Director, Center for Devices and Radiological Health (CDRH), FDA

OPENING REMARKS: Mark McClellan, Commissioner, FDA

Elements of FDA Review for a New Diagnostic Assay: Steve Gutman, Director, Office of In-Vitro Diagnostic Device Evaluation and Safety, CDRH

8:30 – 11:00

SESSION I: Evaluation of SARS Diagnostics

Moderator: TBA

- **Keynotes**

Experience with SARS Laboratory Diagnostics: Malik Peiris, University of Hong Kong

Laboratory Testing in China: Wang Youchun, National Institute for the Control of Pharmaceutical and Biological Products, Beijing

UK Experience: Dr. Maria Zambon, Health Protection Agency, United Kingdom

Break

Real Time under an IDE - CDC's PCR and ELISA Investigational Protocols: Betty Robertson, CDC

Evaluating a New Diagnostic Assay: Industry Perspective – Jim Koziarz, Abbott Labs

NIAID Funding Opportunities: Maria Y. Giovanni, NIH

- **Open Discussion (30 Minutes)**

Break

11:00-11:45

SESSION II - Incorporating Diagnostic Testing into Clinical and Public Health Practice
Moderator: Mark Goldberger, FDA

Clinical Perspective: Joshua Metlay, University of Pennsylvania

Public Health Perspective: Stephen Ostroff, CDC

- **Open Discussion (15 Minutes)**

11:45 – 1:00 p.m.

LUNCH

1:00 – 3:00 p.m.

SESSION III: Specimen and Control Materials for Test Development and Evaluation

Moderator: Janet Nicholson, CDC

- **Keynotes**

WHO Agenda for Test Development & Evaluation: C.E. Roth - CSR/WHO

Experience with Collecting and Banking Specimens: Larry Anderson, CDC

Specimen Handling: Patricia Somsel, Michigan Department of Community Health Laboratory

Using Non-human Sourced and Banked Human Specimen Material for nucleic acid based assay development: David Norwood, USAMRIID

Research Resources: Linda Lambert, NIH

- **Open Discussion (30 min.)**

Break

3:00 – 5:00 p.m.

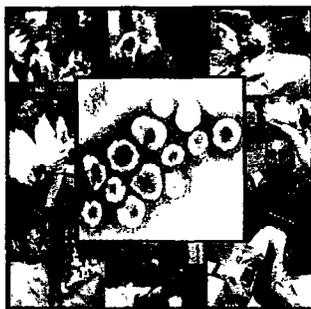
PARTNERSHIPS: ROUNDTABLE - OPEN DISCUSSION

Moderators: David Feigal and Murray Lumpkin, FDA

Keynoters, Moderators, and Audience

5:00 p.m.

WRAP UP AND ADJOURN



Speaker List

FDA Workshop on SARS Diagnostics: Scientific and Regulatory Challenges

Larry Anderson, M.D., Chief
Respiratory Enteroviruses Branch
National Center for Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, MS-A34
Atlanta, Georgia 30333 U.S.A.

David Feigal, Jr., M.D., M.P.H., Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 U.S.A.

Maria Y. Giovanni, Ph.D., Assistant Director
Microbial Genomics and Advanced
Technologies
Division of Microbiology and Infectious
Diseases
National Institute of Allergy and Infectious
Diseases
National Institutes of Health
6610 Rockledge Drive, MSC 6603 Room 5025
Bethesda, Maryland 20892-6603 U.S.A.

Mark Goldberger, M.D., M.P.H., Director
Office of Drug Evaluation Four
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850 U.S.A.

Steve Gutman, M.D., Director
Office of Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health
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2098 Gaither Road
Rockville, Maryland 20850 U.S.A.

Linda Lambert
National Institute of Allergy and Infectious
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National Institutes of Health
6610 Rockledge Drive
Bethesda, Maryland 20892-6603 U.S.A.

Murray Lumpkin, M.D.
Principal Associate Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857 U.S.A.

Mark McClellan, M.D., Ph.D., Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857 U.S.A.

Joshua Metlay, M.D., Ph.D.
Assistant Professor of Medicine
Division of Internal Medicine
Center for Clinical Epidemiology and
Biostatistics
University of Pennsylvania
712 Blockley Hall
Philadelphia, Pennsylvania 19104 U.S.A.

Janet K.A. Nicholson, Ph.D.
Associate Director for Laboratory Science
National Center for Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, MS-C12
Atlanta, Georgia 30333 U.S.A.

David Norwood, Ph.D.
Chief, Systems Development Branch
Diagnostic Systems Division
U.S. Army Medical Research Institute of
Infectious Diseases
Building 1425, Room RL-201
Fort Detrick
1425 Porter Street
Frederick, Maryland 21702-5011 U.S.A.

Stephen Ostroff, M.D., Acting Deputy Director
National Center for Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, Georgia 30333 U.S.A.

Malik Peiris, Professor
Department of Microbiology
The University of Hong Kong
University Pathology Building
Queen Mary Hospital
Pokfulam
Hong Kong SAR

Betty H. Robertson, Ph.D., Deputy Associate
Director for Laboratory Science
National Center for Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, Georgia 30333 U.S.A.

Patricia A. Somsel, Dr.P.H., S.M. (A.S.C.P.)
Director, Division of Infectious Diseases
Michigan Department of Community Health
Laboratory
3350 North Martin Luther King Jr. Blvd
Lansing, Michigan 48909 U.S.A.

Wang Youchun, M.D., Ph.D
Director, Department of Cell Biology
National Institute for the Control of
Pharmaceutical and Biological Products
No.2, Tiantanxili, Chongwen District
Beijing 100050 China

Maria Zambon, BM, BCh, MA, PhD
Deputy Director
Enteric, Respiratory & Neurological Virus
Laboratory,
Health Protection Agency,
Specialist and Reference Microbiology
Division,
61 Colindale Avenue,
London NW9 5HT.
United Kingdom

C. E. Roth, M.D., MRC Path
Project Leader, Dangerous and New
Pathogens
Global Alert and Response
CSR/WHO
20 Av Appia
1211 Geneva, Switzerland



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

July 14, 2003

Welcome to the FDA workshop, "SARS Diagnostics: Scientific and Regulatory Challenges with Diagnostics for Emerging Pathogens". The workshop is being held to serve as a public forum for the academic, clinical, and public health communities (national and international), industry, other government agencies and the FDA to consider data sets that are needed to establish performance for SARs diagnostics. In addition, the workshop will hopefully serve as an opportunity to provide mechanisms for public-private partnerships and sharing of both information and samples to ensure an opportunity for new diagnostics to be studied and used with appropriate labeling. FDA also wishes to promote partnerships among government, industry, health care providers, and the clinical laboratory community that would facilitate the development of new SARS diagnostic assays through sharing of information and resources.

We are pleased to welcome a number of outstanding speakers and participants, including world-wide experts in the field of diagnostic research, as well as officials from industry, and other government agencies.

You are welcome to submit comments on any aspects of FDA's regulation of these products to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: FDADockets@oc.fda.gov.

We greatly appreciate your interest and participation in this important workshop.

Sincerely,

A handwritten signature in black ink, appearing to read "David W. Feigal, Jr.", written over a horizontal line.

David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and
Radiological Health

SPEAKER BIO-SKETCH:

Maria Y. Giovanni, Ph.D.

Maria Y. Giovanni, Ph.D. holds a B.A. in Biology and a Ph.D. in Molecular Biology from the University of Pennsylvania. She did her postdoctoral training in the NIH laboratory of Nobel Prize Laureate, Dr. Marshall Nirenberg in molecular neuroscience. She continued at NIH in 1988 at the National Eye Institute as Director of Fundamental Retinal Processes and then Chief, Retinal Diseases Branch, and she also lead their efforts in Ocular Genomics. In 2000 she moved to the National Institute of Allergy and Infectious Diseases at NIH as Assistant Director for Microbial Genomics and Advanced Technologies and has been involved in leading and coordinating Biodefense and SARS Genomics/Proteomics Resources and Initiatives and Medical Diagnostics for NIAID.

Joshua P. Metlay, M.D., Ph.D.

Joshua P. Metlay, M.D., Ph.D. is a Research Associate in Health Services Research and Staff Physician at the Philadelphia Veterans Affairs Medical Center. He also is an Assistant Professor of Medicine in the General Internal Medicine Division, Assistant Professor of Epidemiology in the Department of Biostatistics and Epidemiology, and Senior Scholar in the Center for Clinical Epidemiology and Biostatistics. He is board certified in internal medicine and holds a Master of Science Degree in Health Policy and Management from the Harvard School of Public Health and a Ph.D. in Immunology from the Rockefeller University.

Dr. Metlay is a current recipient of an Advanced Research Career Development Award from the Health Services Research and Development Service of the Veterans Health Administration and a recipient of a Generalist Physician Faculty Scholar Award from the Robert Wood Johnson Foundation. His work focuses on the relationship between antimicrobial drug prescribing and emerging antimicrobial drug resistance in community settings. Recently, he has conducted a series of projects examining physician decision making in the area of antimicrobial drugs, using both survey and electronic database methodologies. Dr. Metlay is the PI of an NIAID-funded study to develop a clinical prediction rule for patients at risk of drug resistant pneumococcal pneumonia and he is the leader for one of the core projects in the AHRQ-funded Center of Excellence in Patient

Safety at the University of Pennsylvania. Dr. Metlay is also one of the co-Principal Investigators of the University of Pennsylvania's Center for Education and Research on Therapeutics (CERT). The Penn CERT is focused on expanding post-marketing research on the risks and benefits of antimicrobial drug use in both hospital and community settings and translating this knowledge into practice improvement.

Patricia A. Somsel, Dr.P.H.

Dr. Somsel has over 30 years of experience in the private sector in clinical microbiology laboratories. In 2000, she joined the State Laboratory as Director of the Division of Infectious Diseases, which includes three sections: Microbiology, Molecular Biology and Virology. Her previous experience included 8 years of service on a local board of health (with 6 years spent as chair), 5 years as an instructor of clinical microbiology, and 20 years providing consultations on epidemiology and infection control to client nursing homes and hospitals for a large clinical laboratory.

Past research interests have included urinary tract infections in menopausal women and extended care facilities residents, acute otitis media in day care children, and community patterns of developing antibiotic resistance. Current research activities continue in the area of antibiotic resistance in clinical and veterinary isolates, as well as the prevalence and demonstration of non-O157:H7 shiga-toxin producing *E.coli*.

Wang Youchun, M.D., Ph.D.

Dr. Youchun is the Director, National Institute for the Control of Pharmaceutical and Biological Products, which is affiliated with the State Food and Drug Administration (SFAD) of China. He is responsible for quality control of HIV related products. During the period of SARS occurrence, Dr. Youchun's responsibilities include quality control of SARS diagnostics. Additionally, he established lab reference panels and provides clinical evaluation of SARS diagnostics in coordination with staff at the Infectious Hospital in China.

Maria Zambon

Maria Zambon is Deputy Director, Enteric, Respiratory Virus Laboratory, part of UK Health Protection Agency, National Virology Reference Division with >100 scientific/technical/medical staff, and also Director of the WHO National Influenza laboratory. The laboratory is involved in

national virology reference provision and integrated clinical research programmes. Areas of research interest include influenza and respiratory virus diagnosis and pathogenesis. Maria Zambon is the Co-Chair of the International Neuraminidase Susceptibility Network, an international academic/public health/WHO group with responsibility for the oversight of global NI susceptibility monitoring, and the Virology Chair for European Influenza Surveillance 2002/2003 and also the author of various publications on influenza and other respiratory viruses.

ADDITIONAL INFORMATION:

- **We gratefully acknowledge Dr. Koziarz's participation in this workshop. His name is not included on the speaker list, and is listed below:**

James J. Koziarz, Ph.D.
Vice President, Research & Development and Technical
Support
Abbott Laboratories
D-90H AP6C/2
100 Abbott Park Road
Abbott Park, IL 60064-6093

- **The title pages for additional references of interest are found on the tables as handouts for the below materials:**

Practice Guidelines for the Management of Community-Acquired
Pneumonia in Adults.

Guidelines for the Management of Adults with Community-acquired
Pneumonia