U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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VACCINES AND RELATED BIOLOGICAL PRODUCTS

ADVISORY COMMITTEE

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OPEN SESSION 2

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Thursday, November 4, 1999

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The meeting took place in Versailles Rooms I and II, Holiday Inn, Bethesda, Maryland, at 9:00 a.m., Harry B. Greenberg, M.D., Chairman, presiding.

PRESENT:

HARRY B. GREENBERG, M.D., Chairman

NANCY CHERRY, Executive Secretary

ALICE S. HUANG, Ph.D., Member

MARY K. ESTES, Ph.D., Member

ROBERT DAUM, M.D., Member

KWANG SIK KIM, M.D., Member

DAVID S. STEPHENS, M.D., Member

DIXIE E. SNIDER, JR., M.D., M.P.H., Member

BARBARA LOE FISHER, Member

PRESENT (Continued):

PAMELA HARTIGAN, Ph.D., Invited Guest

WILLIAM BRITT, MD., Invited Guest

MARTIN MYERS, M.D., Invited Guest

L. PATRICIA FERRIERI, M.D., Invited Guest

JAY NELSON, Ph.D., Invited Guest

GEORGES PETER, M.D., Invited Guest

STANLEY RIDDELL, M.D., Invited Guest

KAREN GOLDENTHAL, M.D., FDA Representative

CYNTHIA KLEPPINGER, M.D., FDA Representative

JERRY WEIR, Ph.D., FDA Representative

REBECCA SHEETS, M.D., FDA, Representative

DR. ROBERT YETTER, Speaker

C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

(9:04 a.m.)

CHAIRMAN GREENBERG: Good morning, everybody. I'd like to welcome you to the November 4th-5th open session of the VRBPAC meeting.

I haven't seen my co-committee members since the hurricane. I hope all of you got home quickly after the last meeting.

I know you all introduced yourselves for the closed session, but I'd like to redo that for the open session.

Can we start down here at the right, Bob?

DR. DAUM: Good morning. I'm Robert Daum. I'm professor of pediatrics at the University of Chicago.

DR. KIM: I'm Kwang Sik Kim from Children's Hospital in Los Angeles.

DR. SNIDER: Dixie Snider, Associate Director for Science, Centers for Disease Control and Prevention.

DR. HUANG: Alice Huang, Senior Counselor for External Relations from Cal. Tech.

DR. STEPHENS: David Stephens, Emory University School of Medicine, Atlanta.

MS. FISHER: Barbara Loe Fisher, National

Vaccine Information Center.

DR. ESTES: Mary Estes, Professor of Molecular Virology, Baylor College of Medicine.

DR. HARTIGAN: Pamela Hartigan of the Department of Veterans' Affairs Cooperative Studies Program and Yale University.

CHAIRMAN GREENBERG: Harry Greenberg, Stanford University and the Palo Alto VA Hospital.

DR. FERRIERI: Patricia Ferrieri, Professor of Laboratory Medicine, Pathology, and Pediatrics, University of Minnesota Medical School, Minneapolis.

DR. PETER: Georges Peter, Professor of Pediatrics, Brown University School of Medicine and Hasboro Children's Hospital.

DR. NELSON: Jay Nelson, Oregon Health Sciences University.

DR. RIDDELL: Stan Riddell, Fred Hutchinson Cancer Research Center.

DR. BRITT Bill Britt, University of Alabama, Birmingham.

DR. MYERS: Martin Myers, National Vaccine Program Office.

DR. GOLDENTHAL: Karen Goldenthal, FDA.

DR. KLEPPINGER: Cynthia Kleppinger, FDA.

DR. WEIR: Jerry Weir, FDA.

DR. SHEETS: Rebecca Sheets, FDA.

CHAIRMAN GREENBERG: We now have some interesting administrative information to go over.

MS. CHERRY: Good morning, everyone. Let me add my welcome to Dr. Greenberg's.

I have a couple of very short announcements. First of all, I understand that if you've parked in the public lot, be very careful about your meters because the Bethesda police are very careful about your meters.

Also, to tell everyone in the audience that tomorrow we expect to have a very short lunch period, and you may want to make plans appropriately for that.

Now I have this interesting that Harry promised you, which is the reading of the conflict of interest statement. It's a two page statement. So while I read it, this might be a good time for you to put your pagers on silent mode or to turn off cell phones because we ask you not to use cell phones in the room.

This statement pertains to the VRBPAC sessions today, Thursday, November 4th, 1999.

Three of our members, Dr. Ada Adimora, Dr.

Diane Griffin, and Dr. Steve Kohl were unable to attend this meeting. Other members may be arriving later this morning.

We do have some consultants who have been granted privileges as temporary voting members for specific sessions today.

The Director for the Center of Biologics Evaluation and Research, CBER, has appointed Drs. Pamela Hartigan, Patricia Ferrieri, Jay Nelson, Georges Peter and Stanley Riddell as temporary voting members for this discussion on use of chimeric cytomegaloviral candidate vaccines in clinical trials.

For this afternoon's discussion on safety data associated with a fifth successive dose of Tripedia, the CBER Director has extended temporary voting privileges to Drs. Pamela Hartigan, Patricia Ferrieri, John Livengood, and Georges Peter. That's if there are votes.

To determine if any conflicts of interest existed, the agency reviewed the submitted agenda and all financial interests reported by the meeting participants.

Regarding this morning's discussion on CMV, Drs. Robert Daum and Jay Nelson have been granted waivers in accordance with 18 USC 208. These waivers

permit them to participate in the committee discussions and to vote.

Dr. William Britt has been granted a limited waiver, which will permit him to participate in the discussion by sharing his expertise. Dr. Britt will not be allowed to vote on any issues related to the discussions on CMV.

Dr. Harry Greenberg has recused himself from the CMV discussions.

For this afternoon's session on Tripedia, Dr. Edwards has been granted a full waiver under 18 USC 208, which permits her to participate fully and vote on the committee discussions.

Dr. Margaret Rennels has been granted a restricted waiver which allows her to make a presentation and answer questions regarding her presentation, but she is precluded from participating in the committee deliberations, and she may not vote.

Dr. Daum has recused himself from the session on Tripedia.

In accordance with the Food and Drug Administration Modernization Act of 1997, Section 505, Dr. Harry Greenberg has been granted a waiver which permits him to participate fully in the committee discussions on Tripedia.

Several participants disclosed potential conflicts of interest which were deemed by FDA as not sufficient to require waivers, but which did suggest the appearance of conflicts of interest. Written appearance determinations under Section 2635.502 of the Standards of Ethical Conduct have been granted to permit Drs. Edwards, Hartigan, Finkelstein, Riddell and Stephens to participate in the committee discussions on CMV, and to permit Drs. Edwards and Estes to participate in the discussions on Tripedia.

In the event that discussions involve specific products or pharms. not on the agenda and for which FDA's participants have a financial interest, the participants are reminded of the need to exclude themselves from the sessions. Their recusals will be noted for the public record.

With respect to all other meeting participants, we ask in the interest of fairness that you state your name and affiliation, and address any current or previous involvement with any firm whose products you wish to comment on.

Copies of all waivers and appearance determinations addressed in this announcement are available by written request under the Freedom of Information Act.

CHAIRMAN GREENBERG: Thank you, Nancy.

I'd now like to move on to a discussion by Dr. Robert Yetter on the Public Citizen settlement.

DR. YETTER: Good morning. I've been asked to give you some general information about a lawsuit that was filed by --sorry about that -- that was filed by Public Citizen against FDA in January of this year and how the lawsuit has been resolved.

In one of the issues raised by Public Citizen in that suit, they claimed that FDA was not providing redacted copies of advisory committee briefing materials to the public before or at advisory committee meetings, and that FDA's alleged failure to do so violates the Federal Advisory Committee Act.

While the FDA did not admit to the allegations in Public Citizen's complaint, the agency decided to enter into two separate agreements, settlement agreements in July and September of this year.

The September agreement pertains to open advisory committee meetings that are convened by the Center for Drugs, and so I'm not going to go into that particular agreement any further at this time.

The July agreement, however, applies to open, nonapproval issue oriented advisory committee

meetings convened by any center and, therefore, does apply to open, nonapproval issue oriented meetings of this committee.

First I think I ought to explain what a nonapproval issue oriented meeting is and then we'll go to what the agreement actually says.

Nonapproval issue oriented meetings are convened to discuss topics as you might expect other than approval or testing of products. They include meetings that are convened to discuss topics like guidance documents, post approval issues associated with approved products, such as adverse events, withdrawal of products, or post approval monitoring programs.

Advisory committee meetings that are convened to discuss a biologic for which a biologics license application is pending, approval of a biologics license application for a new supplement, or a product for which an investigational new drug application has been submitted, but for which an application to market the product has not yet been submitted are not nonapproval issue oriented meetings. They are not covered by this agreement.

So what does the agreement actually state? What it means is that for the meetings to which it

applies, FDA has agreed, whenever practicable and subject to any applicable exemptions of the Freedom of Information Act, we will make available before or at the time of the open advisory committee meeting convened under the Federal Advisory Committee Act materials provided to the members of the advisory committee for public inspection and copying in advance of the meeting.

I need to emphasize that the FDA is not going to be releasing trade secret or confidential commercial information submitted by the sponsors. This agreement only requires the agency to make publicly available information that is not exempt from release under the Freedom of Information Act.

Are there any questions?

(No response.)

CHAIRMAN GREENBERG: If there are no questions, thank you, Dr. Yetter, and we will now move on to the session on CMV.

Bob.

(Whereupon, at 9:10 a.m., the Open Session 2 was concluded, and the committee reconvened immediately in Open Session 3.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: Vaccines and Related Biological Products Advisory Committee
Session No. 2

Before: DHHS/FDA/PHS/CBER

Date: November 4, 1999

Place: Bethesda, MD

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.