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Meeting with PMA [Pharmaceutical Manufacturers Association] HIV/AIDS Task Force 3/21/94

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Agenda

**Pharmaceutical
Manufacturers
Association**

PMA AIDS Task Force

10th Floor Conference Room
1100 15th Street, NW
Washington, DC 20005

Monday, March 21, 1994
1:00 - 4:00 PM
(lunch will be available at 12:30)

1:00 - 1:10 PM	Review and Approval of Minutes of December 16, 1994 Exhibit I	Dr. S. Carter
1:10 - 2:30 PM	(1) National Task Force on AIDS Drug Development (2) Office of the National AIDS Policy Coordinator (ONAPC) (3) Collaboration between PMA and ONAPC	Kristine Gebbie National AIDS Policy Coordinator
2:30 - 3:00 PM	Intercompany Collaboration on AIDS Drug Development	Dr. S. Carter
3:00 - 3:15 PM	HIV/AIDS Guidelines AHCPR (available at the meeting) PAAC (available at the meeting)	Dr. J. Siegfried
3:15 - 3:30 PM	Data Base for HIV Clinical Trial Sites - Request for Exhibit II	Dr. J. Siegfried

THE WHITE HOUSE
WASHINGTON

3/21 c1

January 12, 1994

John D. Siegfried, M.D.
Associate Vice President
Medical Affairs
Pharmaceutical Manufacturers Association
1100 15th Street, N.W. #900
Washington, D.C. 20005

Dear Dr. Siegfried:

This letter confirms the meeting of Kristine M. Gebbie, National AIDS Policy Coordinator, with the Pharmaceutical Manufacturers Association (PMA) AIDS Task Force, on Wednesday, March 16, 1994.

Ms. Gebbie plans to arrive at 1:00 p.m. to discuss the National Task Force on AIDS Drug Development, the Office of National of AIDS Policy Coordinator (ONAPC) and collaboration between PMA and ONAPC.

Please call me at (202) 632-1090 with any questions or for further clarification. I am enclosing a biographical sketch and curriculum vitae for your reference.

Sincerely,

W. Steve Lee

W. Steve Lee, Executive Assistant
and Scheduler to the
National AIDS Policy Coordinator

Enclosures

John D. Siegfried, M.D.
ASSOCIATE VICE PRESIDENT
MEDICAL AFFAIRS

AA-fgr
**Pharmaceutical
Manufacturers
Association**

January 6, 1994

RECEIVED

Mr. W. Steve Lee
Executive Assistant to
National AIDS Policy Coordinator
Office of the National AIDS Policy Coordinator
750 - 17th Street, N.W., Suite 1060
Washington, DC 20503

JAN 10 1994

Dear Steve:

Thank you for your persistence in helping us schedule a meeting between Kristine Gebbie and the members of the Pharmaceutical Manufacturers Association (PMA) AIDS Task Force. As I indicated in our phone conversation, the Task Force meeting will be on March 16, 1994, from 1:00 to 4:00 p.m. at PMA headquarters, 1100 - 15th Street, N.W., Suite 900, in the District. Ms. Gebbie will be the first agenda item for the meeting, and we will plan that she will be with us from 1:00 to 2:30 p.m. This will accommodate her travel schedule for later in the day.

A copy of the agenda planned for the meeting originally scheduled last September is enclosed. It is still pertinent. It would be helpful for the Task Force to hear from Ms. Gebbie what she sees as her role and the functions of her office and how the newly created National Task Force on AIDS Drug Development impacts her role. Additionally, we are anxious to know how the PMA Task Force might support her role as National AIDS Policy Coordinator.

I will be in contact with you in early March to finalize the agenda. You may contact me at (202) 835-3545 should there be any questions.

Sincerely,

John D. Siegfried
John D. Siegfried, M.D.

JDS:cj
Enclosure
cc: John F. Beary, III, M.D.
Mr. Gerald J. Mossinghoff
PMA AIDS Task Force

America's Pharmaceutical Research Companies

1100 Fifteenth Street NW, Washington, DC 20005 • Tel: 202 835-3542 • FAX: 202 835-3597

Agenda

**Pharmaceutical
Manufacturers
Association**

PMA AIDS TASK FORCE MEETING WITH
KRISTINE M. GEBBIE, R.N., M.N., NATIONAL AIDS POLICY COORDINATOR

Office of the National AIDS Policy Coordinator
750 - 17th Street, N.W., Suite 1060
Washington, DC 20006

Friday
September 17, 1993
9:00 - 10:00 a.m.

- I. Introduction of PMA Attendees
- II. Overview of PMA AIDS Activities and Involvements
Dr. J. Siegfried
- III. PMA AIDS Task Force
Dr. S. Carter
- IV. Pharmaceutical Industry Advisory Panel to the ACTG
Dr. J. Petricciani
- V. Open Discussion Regarding Industry Involvement and Concerns Regarding the AIDS Pandemic

EXECUTIVE OFFICE OF THE PRESIDENT

Washington, D. C.

FAX TRANSMITTAL COVER SHEET

DATE: 17-Mar-94

TO: KRISTINE GEBBIE

SUBJECT: DPC MEETING AGENDA - 3

FROM: ROSALYN A. MILLER (202) 456-2249
ECONOMIC AND DOMESTIC POLICY

If there are any problems receiving this transmission,
please call the sender, or (202) 395-7370.

*Pres Address -
 Apr 29 - Tribal Leaders -
 Press briefing in afternoon
 need info on work done by Tribes
 need for Jennifer O'Connor, Cal. Affairs
 Working Group -
 Tues PM - 3 o'clock -*

March 17, 1994

MEMORANDUM FOR THE DOMESTIC POLICY COUNCIL

FROM: Carol H. Rasco, Assistant to the President for
Domestic Policy

SUBJECT: Meeting Agenda for March 21, 1994

The Domestic Policy Council will meet for its bi-weekly meeting on **Monday, March 21 from 5:30 to 6:30 p.m. in the Roosevelt Room.** Please remember that due to space limitations, this meeting is for principals only or one designee if you cannot be present yourself. If there is to be a designee, please have the clearance information shared with Rosalyn Miller in my office (456-2216).

AGENDA

Domestic Policy Council
Monday, March 21
5:30-6:30 p.m.

Legislative Updates:
The Crime Bill

Attorney General Reno

Education

Secretary Riley

Health Reform

Ira Magaziner

White House Conference on Aging

Secretary Shalala

1995 -

The next meeting will be held on Monday, April 4, 5:30-6:30 P.M. Please remember to call Rosalyn Miller at 456-2216 by the close of business Wednesday, March 30 with suggested agenda items.

cc: Mack McLarty
Phil Lader
Harold Ickes

-2-

Ricki Seidman
Mark Gearan
Christine Varney
Katie McGinty
DPC Staff

3121 c 1:00

November 10, 1993

John D. Siegfried, M.D.
Associate Vice President - Medical Affairs
Pharmaceutical Manufacturers Association
1100 15th Street NW
Washington, DC 20005

Dear John:

I appreciate your patience in trying to schedule a meeting between Kristine and the Pharmaceutical Manufacturers Association AIDS Task Force. As I mentioned, Kristine is out of the country December 16 and 17, but I can make some time available during your January meeting. Please call me at (202) 632-1090 once you set your dates.

Sincerely,

W. Steve Lee, Executive Assistant to
National AIDS Policy Coordinator

John D. Siegfried, M.D.
ASSOCIATE VICE PRESIDENT
MEDICAL AFFAIRS

**Pharmaceutical
Manufacturers
Association**

VIA TELECOPIER

September 14, 1993

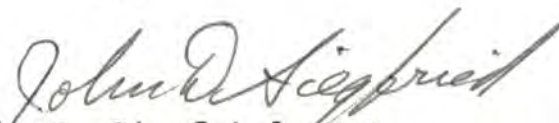
Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator
Suite 1060
750 - 17th Street, N.W.
Washington, DC 20006

Dear Ms. Gebbie:

Enclosed are a proposed agenda and a list of attendees for the meeting of representatives of the Pharmaceutical Manufacturers Association's AIDS Task Force with you on Friday, September 17, at 9:00 a.m.

We look forward to the initiation of a productive dialogue.

Sincerely,


John D. Siegfried, M.D.

JDS:cj

Enclosures

cc: Kenneth R. Brown, M.D. (Merck)
Stephen K. Carter, M.D. (Bristol-Myers)
Ms. Barbara G. Johnston (Hoffmann-La Roche)
Sarah S. Martin-Munley, Ph.D. (Astra)
Ms. Margaret Maruschak (Bristol-Myers)
John C. Petricciani, M.D. (Genetics)
Mr. William J. Rich (Amgen)

Agenda

**Pharmaceutical
Manufacturers
Association**

PMA AIDS TASK FORCE MEETING WITH
KRISTINE M. GEBBIE, R.N., M.N., NATIONAL AIDS POLICY COORDINATOR

Office of the National AIDS Policy Coordinator
750 - 17th Street, N.W., Suite 1060
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Friday
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- III. PMA AIDS Task Force
Dr. S. Carter
- IV. Pharmaceutical Industry Advisory Panel to the ACTG
Dr. J. Petricciani
- V. Open Discussion Regarding Industry Involvement and Concerns Regarding the AIDS Pandemic

LIST OF ATTENDEES

PMA AIDS TASK FORCE MEETING WITH KRISTINE GEBBIE
SEPTEMBER 17, 1993

Kenneth R. Brown, M.D.
Executive Director, Worldwide
Regulatory Liaison, Biologics/Vaccines
Merck Research Laboratories

Stephen K. Carter, M.D.
Senior Vice President, Clinical Research and Development
Bristol-Myers Squibb Company

Ms. Barbara G. Johnston
Assistant Director, Public Policy and Communications
Hoffmann-La Roche Inc.

Sarah S. Martin-Munley, Ph.D.
Associate Director, Clinical Research
Astra Pharmaceutical Products, Inc.

John C. Petricciani, M.D.
Vice President, Regulatory Affairs
Genetics Institute, Inc.

Mr. William J. Rich
AIDS Clinical Studies Team Leader
Amgen, Inc.

John D. Siegfried, M.D.
Associate Vice President, Medical Affairs
Pharmaceutical Manufacturers Association

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IN DEVELOPMENT NEW MEDICINES FOR AFRICAN AMERICANS

Presented by the Pharmaceutical Manufacturers Association

1993 Survey

120 Medicines in Development for Diseases Of Major Concern to African Americans

The data show that African Americans have special health-care needs. For example:

- The death rate for cardiovascular disease is 39 percent higher for African American males than for white males, 68 percent higher for African American females than for white females.

- Although sickle cell disease does not exclusively affect African Americans, 99 percent of those who die from the disease are African Americans.

- The prevalence of diabetes is about 30 percent higher in African American adults than white adults.

America's pharmaceutical research industry is working to meet the special healthcare needs of African Americans. The Pharmaceutical Manufacturers Association (PMA) has found that 120 medicines are in development for diseases that disproportionately affect African Americans or are one of the top 10 causes of death for African Americans. (See "Facts about Diseases/Conditions Affecting African Americans" on page 9 for information about the social and economic impact of these diseases.)

An accompanying article by Richard A. Levy, Ph.D. (see page 17), emphasizes other reasons why the needs of all people—including all racial and ethnic minority groups—must be considered in discovering, developing and testing new drugs. Not all people respond in the same way to the same drug, and it is now clear that racial and ethnic factors may affect drug responses. Racial and ethnic differences may cause people to metabolize drugs differently, have different clinical responses and experience different side effects. For example, African American and white patients differ significantly in their responses to such heart drugs as beta-blockers, ACE inhibitors and diuretics.

All of the medicines listed in this report are in human clinical trials or are at the Food and Drug Administration for review.

Key findings of the survey include:

SUMMARY OF SURVEY RESULTS

• Total Medicines in Development for African Americans	120
• Total Companies Developing Medicines for African Americans	50

SURVEY RESULTS BY DISEASE CATEGORY

	1993
• AIDS/HIV Infection	21
• Blood Diseases	5
• Cancer	20
• Diabetes	14
• End-Stage Renal Disease	5
• Glaucoma	1
• Heart Disease/Hypertension	28
• Respiratory Disorders	25
• Stroke	7
• Tuberculosis	1

SURVEY RESULTS BY DEVELOPMENT STATUS

	1993
• Phase I	23
• Phase I/II	7
• Phase II	41
• Phase II/III	5
• Phase III	45
• Phase I/II/III	1
• Phase Unspecified	3
• Applications Submitted	10

TOTAL RESEARCH PROJECTS

(reflects medicines in development for more than one use)	135
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- The four major categories of focus for research are heart disease with 28 medicines in development, respiratory disorders with 25, AIDS/HIV infection with 21, and cancer with 20.

- The three major causes of death among African Americans—heart disease, cancer and cerebrovascular disease—are the focus of 45 percent of the research projects represented in this survey report.

- Fourteen medicines are in development for diabetes, the fourth leading cause of death by disease among African Americans.

- Five medicines are in development for sickle cell disease.

- More than 40 percent of the research projects listed in this report are in their final stages of development.

- The 120 medicines in development involve 135 research projects

because some of the drugs are being tested for more than one use.

To identify the diseases covered by this survey, PMA worked with the International Coalition of Women Physicians, the National Association for the Advancement of Colored People, the National Association for Sickle Cell Disease, the National Medical Association, the National Black Child Development Institute and the National Black Nurses' Association. We thank these organizations and the other 53 cooperating organizations listed on the back page.



Gerald J. Mossinghoff
President
Pharmaceutical Manufacturers Association

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IN DEVELOPMENT AIDS MEDICINES DRUGS AND VACCINES

Presented by the Pharmaceutical Manufacturers Association

1992 Survey Report

91 Medicines in Testing; 3 Approved This Past Year

Pharmaceutical industry research and development to find medicines to treat, prevent, and cure AIDS and AIDS-related conditions has never been stronger, according to a new survey by the Pharmaceutical Manufacturers Association. Three new medicines have been approved since our last survey a year ago; another 11 medicines are awaiting approval at the Food and Drug Administration. In all, 17 medicines have been approved for AIDS and AIDS-related conditions; 95 research projects, involving 91 separate medicines, are under way.

With the dramatic increase in cases of AIDS in women, as well as its continued incidence in children, this PMA survey has identified, for the first time, clinical trials that focus on meeting the specific requirements of women and children with AIDS. The survey results show that there are 50 medicines in development that include women in the human clinical trials and 13 medicines that include children.

As of this report, there are 17 approved therapies for AIDS and AIDS-related conditions on the market, compared with one when we conducted our first survey in 1987. Three new medicines have been approved for use since our last report a year ago: one for HIV infection, the other two for opportunistic infections. HIVID (zalcitabine) from Hoffmann-La Roche is approved in combination with Retrovir for treatment of adult patients with advanced HIV infection who have demonstrated significant clinical or immunologic deterioration; Nizoral (ketoconazole, oral solution) and Sporanox Capsules (itraconazole), both from Janssen Pharmaceutica, are approved for specific types of fungal infections. Our survey results also show that 41 medicines—almost half of those in

SUMMARY OF SURVEY RESULTS	1987	1988	1989	1990	1991	1992
• Approved Medicines	1	2	9	11	14	17
• Medicines/Vaccines in Development	27	46	55	62	88	91
• Companies Developing Medicines/Vaccines	30	39	39	40	64	66
RESULTS BY DEVELOPMENT STATUS	1987	1988	1989	1990	1991	1992
• Phase I	15	13	22	18	28	26
• Phase I/II	3	10	13	25	15	11
• Phase II	2	12	11	7	22	23
• Phase II/III	3	4	8	18	18	17
• Phase III	2	6	6	14	16	15
• Phase I/II/III	0	0	1	0	0	0
• Applications Submitted	1	3	1	1	5	11
• In Clinical Trials	1	2	3	0	0	1
RESULTS BY PRODUCT CLASS	1987	1988	1989	1990	1991	1992
• Antivirals	15	13	17	27	34	30
• Cytokines	*	*	11	16	12	12
• Immunomodulators	12	25	7	10	12	13
• Anti-infectives	*	6	16	19	23	23
• Vaccines	0	2	2	2	7	8
• Others	*	*	2	3	8	9
TOTAL RESEARCH PROJECTS†	27	46	55	77	96	95

* Category was not included in survey that year.

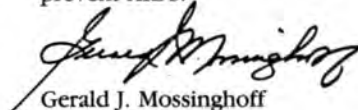
† Reflects medicines in development for more than one use.

testing—are in development to treat opportunistic infections, which account for 90 percent of AIDS-related deaths.

There are now 91 AIDS medicines and vaccines in development, up from 88 in testing last year. These medicines are being developed by 66 pharmaceutical companies. Of the 91 medicines in development, 11 are at the FDA for review—more than double last year's number.

The research-based pharmaceutical industry's efforts so far have led to progress against this devastating disease. New medicines have made

some AIDS-related infections more controllable, which has increased life expectancy. And, in many cases, the quality of life for people with AIDS has been improved. We hope this report will be useful to all of those working in the critically important area of striving to find ways to cure and, one day, prevent AIDS.



Gerald J. Mossinghoff
President
Pharmaceutical Manufacturers Association

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IN DEVELOPMENT NEW MEDICINES FOR WOMEN

Presented by the Pharmaceutical Manufacturers Association

1993 Survey

301 Medicines in Testing for Use by Women

This survey of "New Medicines in Development for Women" shows that America's pharmaceutical research companies—with a massive research and development effort targeted at women's special health needs—are committed to improving the health and welfare of women.

The new survey shows that 301 medicines are in development for diseases that affect only women, disproportionately affect women or are among the top 10 causes of death in women. The medicines now being studied cover nine therapeutic areas that include the major causes of death for women—heart disease, cancer and stroke—and conditions that can severely limit a woman's mobility, such as arthritis and osteoporosis.

Thirty-eight additional medicines have entered human clinical trials since the first PMA survey of new medicines for women in 1991. Eighty-four companies are involved in developing the 301 new medicines.

Some of the medicines listed in this report are in development for more than one use, resulting in 430 separate research projects. Key survey findings include:

- The top four categories of pharmaceutical research for diseases that affect women are cancer with 73 medicines in development, obstetric and gynecologic conditions with 62, cardiovascular and cerebrovascular diseases with 52 medicines in development, and arthritis and other musculoskeletal conditions with 40.
- Nearly half of the research projects listed in this report focus on the three leading killers of women—heart disease, cancer and stroke. (See "Facts about Diseases/Conditions Affecting Women" on page 21 for more information about the social and economic impact of these diseases.)
- Of the 73 medicines in development for cancer, 42 are in development for lung cancer and 52 for breast cancer—the two leading cancer killers of women. Many of these medicines

SUMMARY OF SURVEY RESULTS

	1991	1993
• Total Medicines in Development for Women	263	301
• Total Companies Developing Medicines for Women	79	84
• Total Therapeutic Categories Surveyed*	9	9

*Doesn't include diseases in "Other" category.

SURVEY RESULTS BY DISEASE CATEGORY

	1991	1993
• Arthritis/Musculoskeletal	37	40
• Cancer	58	73
• Cardiovascular/Cerebrovascular	48	52
• Kidney/Urologic	15	13
• Neurologic	16	17
• Obstetric/Gynecologic	51	62
• Ophthalmic	6	8
• Psychiatric	21	19
• Respiratory	17	23
• Other	15	23

SURVEY RESULTS BY DEVELOPMENT STATUS

	1991	1993
• Phase I	42	46
• Phase I/II	15	18
• Phase II	79	121
• Phase II/III	8	21
• Phase III	111	143
• Phase I/II/III	5	65
• Phase Unspecified	19	4
• Applications Submitted	76	12

TOTAL RESEARCH PROJECTS

	1991	1993
(reflects medicines in development for more than one use)	355	430

are being studied for more than one type of cancer.

The Food and Drug Administration has approved 23 medicines that were listed in the 1991 survey. Those medicines are for:

- Asthma—Tilade (Fisons);
- Congestive Heart Failure—Manoplax (Boots);
- Contraception—Depo Provera (Upjohn), Desogen (Organon), OrthoCept (Ortho-McNeil), Ortho-TriCyclen (Ortho-McNeil);
- Depression—BuSpar (Bristol-Myers Squibb), Paxil (SmithKline Beecham), Zoloft (Pfizer);
- Obstetric and Gynecologic Conditions—Prepidel Gel for cervical ripening during childbirth (Upjohn), Zoladex for endometriosis (Zeneca);
- Hypertension—Probeta (Lederle);
- Infections—Floxin (Ortho-McNeil),

Lorabid (Eli Lilly), Omnidox (Abbott), Vantin (Upjohn), Zithromax (Pfizer);

- Migraine Headache—Imitrex (Glaxo);
- Osteoporosis—Ogen (Abbott);
- Osteoarthritis and Rheumatoid Arthritis—Daypro (Searle), Relafen (SmithKline Beecham);
- Ovarian Cancer—OncoScint OV103 (CYTOGEN), and Taxol (Bristol-Myers Squibb).

PMA is grateful to the 70 organizations that have joined in presenting this information. Their names are listed on the back of this report.



Gerald J. Mossinghoff
President

Pharmaceutical Manufacturers Association

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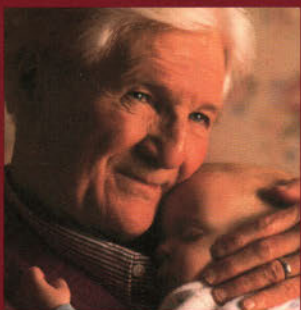
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Pharmaceutical
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