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Invitations June 1995

Stack:	Row:	Section:	Shelf:	Position:
S	66	5	9	2

WAIT until Friday — after conversation w/ Eric Goosby

EJ
Scheduling
Can do Friday. Conflict Thursday
yes remarks?
done
June 30
Jane Sandrelle

Office of HIV/AIDS Policy

Office of the Assistant Secretary for Health
U.S. Public Health Service/DHHS
200 Independence Avenue, S.W. Rm. 733-E
Washington, D.C. 20201
Tel. (202) 690-5560

To: Jeff Levi, ONAP

Fax: 632-1096

From: Terry Beswick
Research Liaison
direct line: (202) 690-7328
Fax. (202) 690-6584
e-mail: tbeswick@oash.ssw.dhhs.gov

Date: 5/23/95

This fax contains 2 page(s) + cover

Comments:

As discussed, here's the draft agenda for the next meeting of the AIDS drug Task Force, currently under review by Task Force members. Please let me know whether Patsy would like to talk. The subject of her remarks is entirely open - we can offer talking points if you like.

Incidentally, Patsy should have received separately from Eric a request for comment on preliminary *draft* subcommittee recommendations which will be discussed on the first day of this meeting. We are consulting with a wide variety of relevant Administration agencies and offices on these proposals, and will be revising and whittling these down to 5 - 7 proposals prior to the meeting. We'll keep you informed as we progress.

NATIONAL TASK FORCE ON AIDS DRUG DEVELOPMENT

June 29 & 30, 1995
Omni Shoreham Hotel, Washington, DC

Draft Agenda

Thursday, June 29

8:00 a.m. **Registration**

9:00 **Introductions and Overview**
Philip R. Lee, M.D., Chairman and Assistant Secretary for Health
Eric Goosby, M.D., Director, Office of HIV/AIDS Policy
Dan Hoth, M.D., Cell Genesys, Inc.

9:15 **Patent and Market Exclusivity Proposals**

Panelists: Representative, Patent and Trademark Office
Representative, Food and Drug Administration

10:15 Break

10:30 **FDA Regulatory Proposals**

Panelists: Representative, Food and Drug Administration
Representative, National Performance Review

11:45 **Public Comment**

12:15 Lunch (on your own)

1:15 **Reimbursement Proposals**

Panelists: Representative, Office of Management and Budget
Representative, Health Care Financing Administration

2:15 Break

2:30 **Tax Proposals**

Panelists: Representative, Office of Management and Budget
Representative, Department of the Treasury

3:30 **Discovery Subcommittee Proposals**

Panelists: David Ho, M.D., Director, Aaron Diamond AIDS Research Center
Harold Varmus, M.D., Director, National Institutes of Health

4:00 **Public Comment**

4:30 **Review and Finalize Task Force Recommendations**

5:30 **Adjourn**

Friday, June 30

7:30 a.m. **Registration**

8:30 **Remarks**
Patsy Fleming, Director, Office of National AIDS Policy (invited)

8:45 **Pediatric Working Group Update**

9:15 **Protease Inhibitor Development Updates**

9:30 **Review HHS, PTO Responses to January Recommendations**

11:00 **Public Comment**

11:30 **Future Plans for the Task Force**

12:30 **Adjourn**

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G1407
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June 30 mtg

Date Rcvd: 05 May 95

From: American Enterprise Institute

Staff Action:

Jeff Levi **RCVD:**_____ **DONE:**_____

Assigned To: CP — Please fax this to Derek Link at 456-1375 done 5/10/95

RCVD:_____ **DONE:**_____

(2) Same for PF

Reviewed By Jeff:_____ **Reviewed By: Patsy** ✓

Action for Staff:

Recommendation/Instruction:

Support Staff:_____

Date of Response:_____

American Enterprise Institute for Public Policy Research

Conference Summary

Reforming the Food and Drug Administration: The Pharmaceutical Approval Process

Members of Congress and congressional staff, government regulators, and scholars met in the U.S. House of Representatives Rayburn Building on March 10 for AEI's seminar, "Reforming the Food and Drug Administration: The Pharmaceutical Approval Process." The session, which was moderated by AEI resident scholars Robert B. Helms and John E. Calfee, considered ways to accelerate the approval of new drugs and to reform outmoded restrictions on the dissemination of product information by pharmaceutical manufacturers. An edited summary of the conference presentations follows.

Sam Peltzman, Sears Roebuck Professor of Economics and Financial Services, University of Chicago Graduate School of Business

I am deeply skeptical that the Food and Drug Administration itself will ever change the new drug introduction process. There are two reasons for this. First, the drug industry has adapted itself to the FDA methods and thus does not have any interest in fundamental change. It is now increasingly common for developers of promising new drug technologies to merge with the big players in the industry to take advantage of their skill in shepherding drugs through the FDA. For the pharmaceutical industry, that practice has become valuable capital that could be substantially eroded through fundamental change at the FDA.

Second, there is no strong popular dissatisfaction with the system. From afar, it seems to work quite well. The truth is that the FDA's exemplary safety record is nothing short of a continuing national disaster. It does not take sophisticated cost-benefit analysis to understand that a risk management system that filters out almost all harm has gone too far.

The only way to get fundamental change is to reduce the FDA's virtually open-ended power. One way to do that would be to impose a legal deadline after which new drug applications would be approved automatically if they are not denied. That was the status quo before 1962. If that is too radical, we could allow a drug to go on the market after a date certain in an approval-pending status. We could also move to increase regulatory competition by giving several agencies the authority to decide which drugs get on the market, at least for certain segments of the population.

The FDA's regulation of prescription requirements is another area ripe for reform. Studies have shown that deregulating the classification of numerous drugs from prescription-only to over-the-counter status will save millions of consumers the time and expense of unnecessary doctor visits. This could be done through a sunset law, by which any drug that has been on the market ten years or that has been prescribed 100 million times would be granted over-the-counter status automatically, unless the FDA

shows cause why it should not be.

I fear, however, that unless this agency is pushed legislatively, its occasional and praiseworthy efforts at internal reform are likely to be overwhelmed by the bureaucratic pressure to continue business as usual.

Louis Lasagna, dean, Sackler School of Graduate Biomedical Science, Tufts University

These are crucial times in the medical history of our country. Far too many life-destroying diseases remain untreated or poorly treated by current medical practices. That is why the complacent attitude of today's FDA is a luxury we can no longer afford. Permit me to list some of the main faults of the current system.

The review and approval time for most products is still too long. Supplemental new drug applications take longer to review than the original new drug applications (NDAs). The labeling of many drugs is out of date and fails to include applications judged by experts to be perfectly acceptable.

Under today's regulations, biotechnology firms are routinely required to establish license applications and to construct and operate full-scale commercial plants before clinical trials of their products are completed, even when no justification for such exceedingly burdensome demands exists. Summary presentations of pivotal data are not trusted by the FDA, forcing painstaking reanalysis. Far too many clinical holds halt the progress of research on humans. And manufacturers are forbidden to distribute information on new uses of approved drugs unless it is specifically requested by individual physicians.

My list of possible reforms would include early and continuing collegial discussions between the regulators and the regulated throughout the investigational new drugs (IND) process (so that NDAs may one day become almost self-reviewing) and a scientific appeal mechanism that would work fairly and rapidly. The FDA should acknowledge that its mission is both to protect and to promote the public health. The agency's paternalistic attitude that prohibits the export of drugs and biologicals not approved in the United States—even to countries that have approved them—should also be changed. I also see no reason why perhaps 1,500 to 2,000 of the INDs filed each year could not be investigated by contract research organizations or physician review boards. Among other benefits, this would free up FDA personnel for more important matters.

J. Howard Beales III, associate professor of public policy, George Washington University

One of the great ironies of our current regulatory regime is the fact that although physicians may prescribe FDA-approved drugs for any use, manufacturers are permitted to provide information only about the specific uses for which the agency approved their products. However well intentioned this regulation may be, the practical result is that physicians are often ignorant about medically proven, scientifically sound uses of approved drugs until the FDA grants approval for those new uses. I suggest that we permit manufacturers to disseminate alternative drug-use information that has a sound scientific basis and prohibit such dissemination when it does not.

Pharmaceutical companies have powerful incentives to make information available not only about new uses of their products but also about the costs of their products relative to those of their competitors or about drug therapies versus surgical alternatives.

There may be more than one right answer to the question of the most cost-effective choice. Clearly, we cannot design clinical trials to examine each and every possibility on the basis of cost effectiveness. At the same time, restricting cost-effectiveness claims by manufacturers may cut off a potentially valuable source of information that could lead to better decisions. Partial ignorance may be undesirable, but it is better than complete ignorance.

William B. Schultz, deputy commissioner for policy, FDA

The complaint has been made that the FDA takes too long to approve new drugs, particularly in cases of breakthrough or life-saving pharmaceuticals. I am pleased to report that by 1997, the FDA will make its decisions on all prescription drugs, breakthrough or not, within twelve months. If the drug is a significant advance over what is currently available, we will decide within six months.

Those changes will occur because of the Prescription Drug User Fee Act of 1992, a law that gave the FDA the resources it needed to hire additional staff to review and approve prescription drugs. Once that new schedule is in place, the United States will be as fast as or faster than any country in the world in making decisions on prescription drugs.

The user-fee program set interim goals that had to be met in 1994, 1995, and 1996. So far, the FDA has met every one of those goals. It expects to meet them this year, and I have every confidence we will also reach the major goals that this bill envisioned by 1997.

As part of Vice President Gore's process of reinventing government, the FDA is taking a serious look at all its regulations—not just for drugs but for medical devices, foods, and the other products that it regulates. The agency will soon announce significant steps to streamline industry requirements and save agency resources, without undercutting the public health.

At the same time, I view the proposals expressed here and elsewhere to allow companies to advertise unapproved uses of their products as a major—and not entirely beneficial—change for the medical consumers of this country. I am concerned that companies would seek approval for narrow uses of their products and then advertise them for broad or different uses. Today, many patients are reimbursed by the federal government and by insurance companies for their purchases of approved drugs. If the widespread advertising of unapproved uses is permitted, our system of review would have to be radically different, as would this system of insurance reimbursement.

Robert J. Temple, director, Office of Drug Evaluation I, Center for Drug Evaluation and Research, FDA

Critics of the FDA often ignore the value of an institution with not only the knowledge and skill but also the responsibility for monitoring and supervising drug development. Because we see so many examples of new products and follow them closely, we can discover problems and suggest new approaches that would be hard for outsiders to duplicate.

We discovered in the mid-1970s, for example, that almost no one was conducting research on how to determine proper drug dosages. The FDA discovered this omission and, beginning in about 1975, introduced a study designed to determine dose response relationships that is now in wide use worldwide. Getting the right dose is important. There is growing evidence, for example, that the large doses of diuretics used to treat hypertension in the 1960s and 1970s may have had actually lethal effects and robbed people of much of the benefits of antihypertensives.

That is one reason why those of us at the FDA consider reducing regulations on publicizing the unapproved uses of approved drugs such a bad idea. We all welcome additional academic discourse on matters that are not yet resolved scientifically. But drug manufacturers will not be neutral discussants of these controversial matters, and their product promotion is neither education nor open discussion.

Finally, people should realize that there is little difference in the standards for pharmaceutical approval and marketing among the European Community, Japan, and the United States. The international drug-developing community now conducts essentially the same studies in other countries as it does in the United States. Most drugs today are submitted for approval by the regulatory agencies at about the same time worldwide, and the

development time is approximately the same for all countries. We could all be wrong, but we are similar.

Sam Kazman, general counsel, Competitive Enterprise Institute

If today the FDA approves a drug or device that will start saving lives tomorrow, how many people died yesterday waiting for the agency to act? The unknown magnitude of this forgone therapeutic benefit is perhaps the least appreciated cost of FDA regulation.

From the standpoint of public health, victims of unanticipated drug side effects are qualitatively not different from victims of delays in the approval of new drugs and medical devices. Victims of delays, however, do not count for much in terms of heart-breaking news accounts, congressional hearings, or even casual public perception. The result is a deadly excess of caution that cannot be undone easily.

My suggestion is not to abolish the FDA, or even necessarily to change its approval criteria for safety and efficacy. Instead, I would allow unapproved drugs and devices to be available under two relatively strict conditions: first, with clear warning of their unapproved status and, second, only under strict medical supervision. The FDA would thus continue to certify drugs, but it could not veto unapproved drugs.

Likewise, there is no reason that the FDA should be the only institution in the business of certifying drugs. A host of medical entities could get into the activity of evaluating emerging new therapies, subjecting the FDA to competitive pressure for the first time in its history and forcing the agency to earn its credibility.

William M. Wardell, president, Protein Engineering Corporation

There are at least three ways in which today's medical and scientific environment is different from that which prevailed at the time of the FDA's founding. All three should be kept in mind as we consider regulatory or legislative reform.

First, we now have the results of thirty-three years of regulation. In many respects, it has been a spectacular success. Clinical investigation is nearly 100 percent safe. No drugs that are ineffective or grossly unsafe have been marketed since 1962. None of us would ever have dreamed that it would be so easy to achieve these results.

At the same time, the laws and regulations have also achieved negative effects, some of which we have heard about today. We now know how to achieve practically any level of confidence we demand in the safety and efficacy of our pharmaceuticals. If there is a fear that the genie of deregulation could get out of the bottle, we now know we can put it back in again quite easily.

Second, the United States now has a national system of drug development. It may not be as consciously designed or as efficient as one would like, but it is a system through which the rival interests of drug firms, universities, research scientists, the FDA, the National Institutes of Health, lawyers, investigative reporters, and drug consumers all compete. We have complex management systems within these various institutions governing their procedures. The system has redundant protections; removing some would not undo them all.

The third major change is today's completely different marketplace, in which the primary drug customer is likely to be a corporate entity, such as a managed-care organization. In the future, the take-up of a drug after launch will be closely controlled by these corporate purchasers, the health maintenance organizations they service, and the doctors who work for them. I am not advocating this type of system, just pointing out that it is with us and that it will have effects on the drug development system, one of which could be used to accelerate approvals.

Mere tinkering with the FDA approval process will not produce the greatest gains because it will have only a trivial effect on the total time it takes to develop new drugs.

Reform must extend to the controls over the whole development process. Fortunately, the changed medical and scientific environment of the 1990s makes it both feasible and responsible to attempt substantial regulatory relief across the development process. We ought to take advantage of this new environment by obtaining expedited drug development and approval in light of the anticipated controlled utilization under managed health care, as well as the improved postmarketing surveillance safety net we now have.

Peter Barton Hutt, partner, Covington and Burling

There are two ways to reform the FDA: we can wait for the agency to reform itself, or we can seek reform through legislative means.

It has been said today that there are reports on how to reform the FDA's drug approval system going back to 1970. Actually, the first such report was written in *1939*, one year after passage of the Federal Food, Drug, and Cosmetic Act. There have been hundreds of these reports, but what has the FDA done in response? It has basically just invented new terms for the old ways it has always handled the problems.

If we really want change, we cannot suppose that one shred of that change will come from the inside. The hard reality is that we need to pursue legislation that is mandatory and brutally intrusive and that tells FDA officials to do things they do not want to do.

It now takes six months for the FDA to meet with a small biotechnology company to review and approve a protocol for a clinical trial, so that a study that once cost $3 million now costs $6 million. Five years ago, the typical biotechnology company started out with five drug candidates. Now it has but one, not because of scientific problems, but because it does not have the capital needed to see five drugs through the lengthy FDA approval process. These firms are basically auctioning off their crown jewels either to the large firms or to each other, hoping to stay in business long enough to get through the trial phase. Most of them will not make it.

I propose some legislative remedies to help our fledgling biotechnology industry.

Just a few new sentences in the FD&C Act could end the pointless prohibition on the dissemination of information about unapproved uses of approved drugs, could accelerate the pace of clinical trials, and could eliminate the requirement for an environmental impact analysis for every new drug. Another few words could end some of the FDA's excessive regulations on manufacturing practices that have no real impact on public health. We could easily allow a drug to be exported once any sophisticated foreign country has approved such a drug. Each of these reforms could be implemented in a way that would eliminate discretion for the FDA to continue its present policy.

As of February 1, 1995, there is a new agency designed to do for Europe what the FDA is designed to do for the United States: the European Medicines Evaluation Agency (EMEA). Why not have a rule that says that, once the EMEA has approved a new drug, the FDA will have three months to review its administrative record? If the FDA does nothing at the end of three months, the new drug is approved for use in the United States under the conditions specified in the EMEA approval. If the FDA decides to disapprove it, the agency must specify in the Federal Register why the drug is unsafe or ineffective. (It would not be sufficient for the FDA to conclude that there is a lack of evidence of safety or effectiveness; the agency would say that every time.) The introduction of real competition in the process by which we approve new drugs just might be the most significant change of all.

John E. Calfee, resident scholar, AEI

If the FDA operated in the way most government agencies do, firms under its jurisdiction would have a number of tools available when seeking to resist regulatory expansion. They could appeal to higher levels within the FDA or to the secretary of Health and

Human Services. They could go to other parts of the government, such as the National Institutes of Health, or to nongovernmental health authorities and news media. They could even seek judicial remedies in court.

Practically none of this ever happens. The reason why is clear: the FDA's extensive power over many aspects of the pharmaceutical and other industries. A central element of that power is the agency's ability to prevent new products from being introduced and to impose arbitrary new requirements as part of its approval process. As long as pharmaceutical or medical device firms face an agency with that kind of power, they will have a strong incentive not to upset the agency in any of its *other* exercises of power. This has allowed the FDA to leverage its approval authority into a vast power over many other aspects of the pharmaceutical and medical device industry.

This exercise of leveraged power is also at the heart of the problem of public discussion about FDA regulation. As long as we have such a system, the debate over FDA regulation will always be one-sided because public information will always remain one-sided. Skilled FDA spokesmen will tell us in detail what they are doing properly and how they are fixing the little things they concede are wrong. Industry spokesmen, the only ones who possess the necessary facts, will not tell us the whole story because of their natural fear of the FDA and its leveraged power.

The proposals that have been discussed today would go a long way toward ameliorating the adverse effects of FDA regulation, but I fear that not many of them will be adopted. My own proposal would be to divide the agency into several autonomous parts, each of which would have roughly the same responsibilities it does now. One agency would be responsible for approving pharmaceuticals; another would approve medical devices; still another would oversee manufacturing methods and postmarketing surveillance. There would also be a separate agency to regulate advertising, promotion, and information, as was the case when the Federal Trade Commission regulated pharmaceutical advertising before 1962.

If our study of the history of regulation has taught us one thing, it is that agencies work badly when exempted from legal checks and balances. When they make mistakes in the form of heavy-handed or inefficient regulation—and all agencies make such mistakes—they can ignore the adverse consequences of their mistakes because they are not challenged by the industry as they ought to be. The new arrangement I have suggested decreases the FDA's vast scope for leveraged power and restores desired checks and balances to the regulatory process.

[This conference summary was prepared by Sharon M. Utz.] # 5135

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and Services Administration
Rockville MD 20857

Bureau of Health Resources Development

SPEECH

Copy for Richard

FAX TRANSMISSION COVER SHEET

DATE: MAR 14 1995

TO: Patsy Fleming, Director FAX. 1202 632-1096
Office of National AIDS Policy

yes

confirmed on calendar

FROM: Richard G. Schulman, M.S.W., Co-Chair National Meeting

Division of HIV Services (DHS)

Bureau of Health Resources Development (BHRD)

Health Resources and Services Administration (HRSA)

This document consists of 2 pages, including this cover page. Should you have any problems with this transmission, please call the Division of HIV Services at: 301-443-6745. The FAX number for the Division of HIV Services is: 301-443-5271.

Comments: Dear Ms. Fleming:

Thank you for considering our speaking engagement request. If you or your staff wish addtional information, please don't hesitate to contact Miguel Gomez or myself (Co-Chairs, National Meeting) at 301 443-9091.

Thank You..

Richard G. Schulman

Press - House not seen
Q & A
Lower level - Jefferson Room
Connecticut Ave. Entrance

202-483-3000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

BUREAU OF HEALTH RESOURCES DEVELOPMENT

Health Resources and
Services Administration
Rockville MD 20857

MAR 14 1995

Ms. Patricia S. Fleming
Director
Office of National AIDS Policy
750 17th Street N.W., Suite 600
Washington, D.C. 20503

Dear Ms. Fleming:

I am writing to invite you to speak at the 4th Annual Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Title I and II National Technical Assistance Meeting to be held June 28-30 at the Washington Hilton Hotel, Washington, D.C.

Every year we convene our grantees and their representatives -- State and local health departments, local planning bodies, persons living with HIV/AIDS, and community-based organizations -- to assess the progress they are making in meeting the health and human care needs of people with AIDS and HIV and those who care for them. The focus of this year's meeting is on *Future Directions and Challenges for HIV/AIDS Health Care and Service Delivery*. We would be honored if you could present on an HIV issue of your preference, at a working luncheon on the second day of the meeting, Thursday, June 29. Based on interest from grantees in the field, our National Meeting Planning Committee has suggested the topic of *HIV and Health Care in the Current Political Environment*. You should anticipate an audience of approximately 250-300 knowledgeable and concerned people.

Thank you for giving this request your serious consideration. We are aware of the tremendous demands on your time, nevertheless we think you will want to join us and participate in this important meeting. If you have questions or need any further information, please contact Jon Nelson, Chief, Planning and Technical Assistance Branch or Richard G. Schulman and Miguel Gomez, Co-Chairs of the National Meeting, 301 443-9091.

Sincerely yours,

for Anita Eichler, M.P.H.
Director
Division of HIV Services

June 29
12:30 luncheon

NATIONAL TASK FORCE ON AIDS DRUG DEVELOPMENT

June 29 & 30, 1995
Omni Shoreham Hotel, Washington, DC

Draft Agenda

Thursday, June 29

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Dan Hoth, M.D., Cell Genesys, Inc.

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Representative, Food and Drug Administration

10:15 Break

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11:45 Public Comment

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Panelists: Representative, Office of Management and Budget
Representative, Health Care Financing Administration

2:15 Break

2:30 **Tax Proposals**

Panelists: Representative, Office of Management and Budget
Representative, Department of the Treasury

3:30 **Discovery Subcommittee Proposals**

Panelists: David Ho, M.D., Director, Aaron Diamond AIDS Research Center
Harold Varmus, M.D., Director, National Institutes of Health

4:00 Public Comment

4:30 Review and Finalize Task Force Recommendations

5:30 **Adjourn**

Friday, June 30

7:30 a.m. **Registration**

8:30 **Remarks**
Patsy Fleming, Director, Office of National AIDS Policy (invited)

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9:15 **Protease Inhibitor Development Updates**

9:30 **Review HHS, PTO Responses to January Recommendations**

11:00 **Public Comment**

11:30 **Future Plans for the Task Force**

12:30 **Adjourn**

Zhoojann

yes

Accepted 6/2/95

May 24, 1995

MEMORANDUM TO THE DOMESTIC POLICY COUNCIL

FROM: CAROL H. RASCO

SUBJECT: JUNE 12 1995 MEETING

On Monday June 12, the Vice President will be joining us at our regularly scheduled Domestic Policy Council meeting. I hope each of the Cabinet Secretaries and Agency heads can make a special effort to attend.

AGENDA

I. Vice President's Family Conference

The Vice President will discuss plans for the upcoming Family Conference which he and Mrs. Gore have made into an annual event. This year, the Conference will focus on family and the media. The Vice President will be seeking the input of DPC members on how to make the Conference as innovative and effective as possible and to determine how your agencies can best be involved.

II. Community Empowerment Board

For the second half of the meeting, we will be joined by the Vice President's Counsel, Kumiki Gibson, and the Director of the Community Empowerment Board (CEB), Sheryll Cashin. We will be discussing ways to ensure the success of the Empowerment Zone/Enterprise Community Initiative.

Please have your offices respond to Pat Romani at 456-2249 regarding your attendance. Because of the nature of this meeting, we ask, to the extent possible, that there be no substitutes for principals. Thank you.

AIDS Action council

June 1, 1995

Patsy Fleming
Director
Office of National AIDS Policy
The White House
759 - 17th St., NW
Washington, DC 20503

VIA FAX: 632-1096

Dear Patsy Ms. Fleming:

Thank you for agreeing to participate in our board meeting. Here is the meeting information:

Date: Saturday, June 10

Location: National Education Association
Health Information Network
1527 M St., NW
News Conference Room (first floor)
Washington, DC 20036

Time: 9:00 AM - 5:00 PM
Your participation time is at 1:30 PM

Thank you again. If you have any questions please call me (202/986-1300 ext 3011) or my assistant Alice Drew.

With warm regards,

Mark Barnes
Executive Director

enclosure: board list

1875
Connecticut Ave NW
Suite 700
Washington DC
20009
Fax 202 986 1345
Tel 202 986 1300

? ZJ Scheduling conflict on Tuesday

Yes for Wednesday 6/28 OK Same

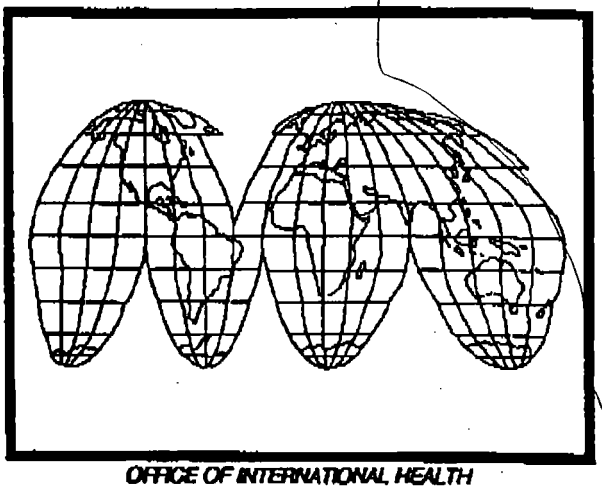
FACSIMILE TRANSMISSION SHEET

FROM:

LINDA A. VOGEL
Director
Office of International Health

Department of Health and Human services
5600 Fishers Lane
Rockville, Md. 20857
RM.16-87

TEL: 301-443-1774
FAX: 301-443-6288
E-Mail: LVOGEL.OASH
Internet: LVOGEL@OASH.SSW.DHHS.GOV



OFFICE OF INTERNATIONAL HEALTH

TO: Patricia Fleming FAX NUMBER: 202-632-1096

DATE: 5/22/95 NUMBER OF PAGES: 3

☐ FYI
☐ AS REQUESTED

☐ FY ACTION
☐ AS DISCUSSED

MESSAGE:

NCIH NATIONAL COUNCIL FOR INTERNATIONAL HEALTH

1701 K STREET, N.W. SUITE 600, WASHINGTON, DC 20006, (202) 833-5900, FAX: (202) 833-0075

April 27, 1995

Dear Organizational Member:

I am writing to assure that you are familiar with the upcoming NCIH AIDS Program Workshop to be held immediately following the 22nd Annual Conference. This year's workshop, **"HIV/AIDS: International Perspectives on Human Rights and Legal Issues,"** will begin at 3:30, Wednesday, June 28 and continue until 5:30 Thursday, June 29. Dr. Peter Piot, the director of UNAIDS, the new United Nations co-sponsored program on HIV/AIDS, has agreed to give the opening keynote speech which will be followed by a reception Wednesday afternoon. The second day will be devoted to relevant panel discussions: *The Impact of Violence on HIV+ and At-risk Populations; HIV/AIDS Legislation: Blame and Responsibility; The Ethics of Vaccine Trials in Developing Countries*; and a strategy planning discussion focusing on the role that NGOs, PVOs and the UN programs can take to combat HIV/AIDS related human rights abuses.

The panel participants and speakers will cover a wide range of professional expertise and geographic experience. This, however, is not enough without an audience of interested and diverse public health professionals. I would like to encourage your organization to become involved. Please copy and distribute the enclosed flyers to anyone you feel may be interested in our workshop. Feel free to call me or Mary Guinn Delaney at (202) 833-5905, with any suggestions or questions. Thank you for your time and commitment to NCIH.

Sincerely,

Kelly Forrest
AIDS Program Assistant/*AIDSLink* Editor

The NCIH AIDS Program announces its 1995 Annual Workshop

HIV/AIDS:
International Perspectives on Legal and Human Rights Issues

June 28 (5:30 - 6:30 pm) - June 29 (8:00 - 5:30)
Crystal City Hyatt Regency, Arlington, VA (Washington metro area), USA
Washington A-B Room

This year the NCIH AIDS Program hopes to spark both discussion and action on the human rights abuses specific to HIV+ and at-risk populations. No one should be denied their rights because they are HIV+ or perceived as being at-risk for contracting HIV. No one should contract HIV because they do not have the power to protect themselves. Effective HIV/AIDS prevention and care are only possible when the basic human rights of every human being are respected, and when individuals have control over their own well-being.

Dr. Peter Piot, Director of the new Joint and Co-sponsored United Nations Programme on HIV/AIDS (UNAIDS) has agreed to be this year's keynote speaker. **Ms. Nan Hunter, Deputy General Counsel at the US Department of Health and Human Services** and an expert on legal issues related to HIV/AIDS, will give the second keynote. The workshop program will consist of both keynote addresses and panel presentations with ample time for discussion and networking. Topics for the panels are: the impact of violence on HIV+ and at-risk populations; legal issues relating to immigration and mandatory testing; and the ethics of vaccine trials in developing countries.

Invited speakers include:

Julia Stachowiak, AIDS Infoshare Russia;
Michael Ratner, attorney, Center for Constitutional Rights;
Carel Ijsselmulden, Transvaal School of Medicine, South Africa;
Lynel Long, Project Officer, Balkans Trauma and Humanitarian Assistance Program, USAID;
Edgar Carrasco, Accion Ciudadana Contra el SIDA (ACCSI), Caracas, Venezuela;
Terry Maroney, New York City Gay and Lesbian Anti-Violence Project; and
Shyamla Nataraj, South India AIDS Foundation.

The last session will be devoted to discussing our roles in preventing HIV/AIDS related human rights abuses. We encourage all of those involved in international HIV/AIDS prevention, care and research, as well as those with an interest in human rights to take part in this workshop. For more information please contact: Mary Guinn Delaney, AIDS Program Manager or Kelly Forrest, AIDS Program Assistant at (202) 833-5905.

Registration fee (NOT included in NCIH Annual Conference registration fee) includes workshop materials, Wednesday afternoon reception and lunch on Thursday. Registration: Before May 20, $35 for NCIH AIDS Network members, $50 for non-members; after May 20 or on-site, $50 for NCIH AIDS Network members, $65 for non-members. After June 16, on-site registration only, please.

Name _____

Organization _____

Address _____

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City _____ State _____ Zip _____

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Fax _____

Form of Payment

☐ Check *(payable to NCIH)*

☐ Visa ☐ Mastercard

_____ _____
account number *expiration date*

_____ _____
signature *date*

Amount	before 5/20	after 5/20
NCIH & AIDS network members	☐ $35	☐ $50
Non-members	☐ $50	☐ $65

To register, please return this form with prepayment to:
National Council for International Health
c/o First American Bank
Department 5100
Washington, D.C. 20061-5100
or Fax (202) 833-0076 *(for credit card orders only)*

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Should we block some of these times on your schedule?

NCIH NATIONAL COUNCIL FOR INTERNATIONAL HEALTH
1701 K STREET, N.W. SUITE 600, WASHINGTON, DC 20006, (202) 833-5900, FAX: (202) 833-0075

MEMORANDUM

TO: Patsy Fleming, Office of National AIDS Policy (202 632 1096)
Mike Feldstein, AID (202 647 1770)
Jeanine Buzy, AID (703 875 4672)
Paul Boneberg, GAAN (415 488 1942)

FROM: Mary Guinn Delaney, NCIH

DATE: 23 May 1995

SUBJECT: Proposed schedule for Dr. Piot's visit to Washington (25-29 June)

I spoke with Frances (Piot's staff person) this morning about his upcoming visit to Washington. As far as I can tell, his firm obligations in Washington to date are as follows:

Monday, 26 June (all day)	New York (?)
Tuesday, 27 June (all day)	World Bank
Wednesday, 28 June (2:00 - 6:00)	NCIH Workshop

This leaves the mornings of Wednesday and Thursday open for the activities we discussed yesterday and other appointments Peter will probably make himself. Without knowing what those other appointments are right now, I propose the following schedule:

Wednesday morning	Meeting with U.S. domestic NGOs (GAAN)
Thursday morning/early afternoon	Briefing with Wirth/Hill visits (State Dept - AID - ONAP)

Peter has a fairly strong preference to leave Washington on a Thursday evening flight, as he is due in Australia on Monday and would like to return to Geneva first.

Piot's staff wrote to Wirth's office on 27 March regarding a possible joint briefing but have not yet received a reply. Mike/Jeanine: Could you coordinate follow-up with Wirth's office on this? Though I don't have a copy of the 27 March letter, it sounded to me like Piot and Wirth had agreed upon a briefing on international HIV/AIDS issues for new members of Congress and their staff -- the details of this briefing have yet to be determined.

I will need to get back to Frances as soon as possible to firm up the dates and times and times for the activities we discussed in our meeting yesterday. I will contact each of you on Wednesday afternoon to follow up. Talk to you then!

Mary Guinn

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ZJ
Sched

GLMA / AAPHR
273 Church St., San Francisco, CA 94114 • ph: 415-255-4547 • fax: 415-255-4784
Founded in 1981 as the American Association of Physicians for Human Rights

must be open 1:00 pm 6/27.
scheduled 1:00
done

Via Fax

To:	Patsy Fleming
Organization:	
Fax Number:	202-632-1096
Phone Number:	1090
From:	Ben Schatz, JD
Date:	5-24-95
# of Pages to Follow:	None

Comments:

I'm going to be in D.C. on June 27 + 28 and would very much like to meet with you. Do you have any availability on the 27th any time beginning 11:00 a.m or on the 28th until approx. 2:30? Please let me know. Thanks. Hope you're well

XOXO

Ben