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Correspondence - SLT - Incoming - 4/97 [3]

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. letter	Concerned citizen to Sandra Thurman re: Personal plan to combat AIDS (19 pages)	04/28/1997	b(6)
001b. envelope	re: Concerned citizen to Sandra Thurman (1 page)	04/28/1997	b(6)

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Clinton Presidential Records
National AIDS Policy Office

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RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Post-it® Fax Note 7571		Date	# of pages 2
To SANDY THURNER	From Michael McShane		
Co./Dept	Co.		
Phone #	Phone # 703.276.5040		
Fax #	Fax # 703.276.5057		



Subject:
The Agenda For The United
States/European Union
May 5-6 International Business
Conference

Date:
April 16, 1997

From: 
Michael J. McShane

To:
Sandy Thurman

cc:
Tom Stillitano

Phone/Fax
703. 276.5040/5057

Sandy:

Thanks for the opportunity to review and comment, from an international business perspective, on the proposed United States/European Union agenda for their May 5-6, 1997 Transatlantic Business Conference on "Building Bridges Across the Atlantic."

From an international business perspective, the conference agenda, as now structured, has some significant weaknesses. Primary among those is the overall thrust and tone of the agenda. Not surprisingly, and as might be expected of an agenda drawn up by individuals responsible for policy, the agenda is geared toward general policy discussions. It is not geared toward the specific needs of the business community. It does not address or foster specific discussions of relevant and pressing business issues that effect today's business bottom line.

For example, a discussion of Business and Vocational Partnerships is an interesting policy discussion. However, in a business context, that subject lacks the imperative and immediacy of discussions and negotiations on reducing, for example, international structural and tariff barriers to trade and telecommunications initiatives or the establishment and operation of free trade zones and agreements.

The tone and thrust of the agenda works against the needs and interests of the international business community and explains the lack of interest on their part in the Conference. An agenda geared to the more specific needs, issues and interests of international business will, I am sure, trigger a more enthusiastic response to the Conference from the international business community.

I hope this memo is helpful and I look forward to working with you to help restructure the agenda.



UNITED STATES INFORMATION AGENCY
WASHINGTON, D.C. 20547

Office of Citizen Exchanges

4 - 10

Sandy - You were
going to help w/
Leon Panetta & a
project. Any
chance?

Carl

LAWS grant summary
April 2, 1997

1. The grant is to the Lawyers' Alliance for World Security (LAWS) on the theme of Executive-Legislative Relations. Activity so far:

a. December, 1993: One of President Yeltsin's key staff members, Anatoliy Sliva, came to Washington; among others, he met with Thurgood Marshall, Jr., Howard Paster, Steve Ricchetti, and Bernard Nussbaum (see attachment A). At the time, Mr. Sliva was Deputy Director of the (Russian) President's State-legal Administration. He since has become Plenipotentiary Representative of the President to the Federation Council.

b. May, 1995: A workshop on legislative policy and lobbying was held in Moscow with U.S. White House and Russian presidential staff participating. Americans included John Podesta and David Dreyer. A list of Russian participants and program information is at attachment B.

c. July, 1995: Three of President Yeltsin's senior advisors came to Washington for meetings with Pat Griffin and Steven Richetti in the White House, bipartisan Congressional staffers, and others. An itinerary, names of the participants, and additional program information is at attachment C.

2. Next and final phase of the grant: a one-and-one-half day seminar in Moscow. Topics to be covered and additional information are set forth in attachment D. This possible seminar has been discussed with members of the Russian Presidential Administration by Embassy Moscow's political section and the LAWS project director, Anthony (Tony) Sager. The Embassy hopes the seminar will take place because it will help cement relationships with the Russian Administration. The Russians are interested and have indicated that the level of participation will depend on who comes from the United States.

3. Tony's first choice to lead the American delegation is Leon Panetta. Tony would also like to see Patrick Griffin, Doug Sosnik, and a communications strategy person participate. Once the head of the delegation is finalized, it will be easier to get others on board.

4. Tony has approached Mr. Panetta twice, once through former participant John Podesta and once directly (see attachment E). Tony's rationale for wanting Mr. Panetta is explained in a memo sent by him today to E/PN (attachment F): President Yeltsin has a brand new chief of staff with some obvious weaknesses, and Mr. Panetta's participation is likely to engage the interest of this new Russian chief, Valentin Yumashev.

5. The seminar could take place almost anytime in May or June, as long as all travel is completed by the end of June when the grant expires.

SCHEDULE for RUSSIAN PRESIDENT'S STATE-LEGAL ADMINISTRATION (1)

WASHINGTON, DC DECEMBER 12-18, 1993

LAWMAKING FOR DEMOCRACY PROJECT / LAWYERS ALLIANCE FOR WORLD SECURITY

	Monday, Dec. 13	Tuesday, Dec. 14	Wednesday, Dec. 15	Thursday, Dec. 16	Friday, Dec. 17
Breakfast	At Hotel*	At Hotel	At Hotel	At Hotel	At Hotel
Morning	10:00 am "Legislative Relations of a National Security Agency" - William Colby, fmur Dir., CIA 1250 24th St., NW 11:30 am House Foreign Affairs Cmte Staff Mtg 2173 RHOB <i>Mike Van Deusen Chris Keyser</i>	9:30 am "Planning and Implementing the President's Legislative Strategy" - Nicholas Caleo, Pres. Bush's Director of Legislative Relations 1350 I St., Ste 690	10:00 am "Coordinating Strategy with the Executive" - T. O'Donnell, Chief of Staff to House Majority Leader H-148 [11:30 Wm. H. Brown, House Parliamentarian]	9:00 am "Budgetary & Tax Aspects of Federalism" - Jim Martin, National Governors' Assoc. 400 No. Capitol St.	9:30 am "Why is the American Judiciary Independent?" - Abner J. Mikva, Chief Judge, U.S. Court of Appeals DC Cir. 333 Constitution Ave., NW [10:45 am Advocacy Inst.]
Lunch	[House Member's Dining Room]	Cafe	12:30 pm House Foreign Affairs Subcmte Staff - Lunch & Discussion 2255 RHOB <i>Brad Gindoff + Amit Pandya Bernstein's Subcommittee</i>	1:00 pm Isaac Shapiro & Diana Lopez of Skadden, Arps Law Firm La Colline	12:00 pm "Legis. Strategy for Treaty Ratification" - Amb. Ralph Earle Crowell & Moring 11B
Afternoon	<i>RS</i> 2:00 pm Thurgood Marshall, Jr., Legal Counsel to Vice-Pres. Gore S-212 4:00 pm "Legislative Drafting Process" - Roger Young, Dep. House Legis. Counsel 136 CHOB	<i>RS</i> 1:30 pm "Lobbying for the President" - <u>Howard Paster</u> , Dir., Ofc of Legis. Affairs 2:00 pm "Legislative Strategy" - <u>Steve Ricchetti</u> , Dep. Director, Office of Legis. Affairs 4:30 pm "Lobbying for Business Clients" - Tony Podesta 1001 G St. Ste 900 East	2:00 pm Meet L. Marks & P. Fleming at Old Ebbitt Grill 3:00 pm "Role of the President's Lawyer" - President's Legal Counsel <u>Bernard Nussbaum</u> WH - NW Gate [5:00 pm Advocacy Institute - D. Cohen & K. Sheekey for Fri. a.m.]	2:45 pm "Forming Legal Policy" - Walter Dellinger, Assis. Att'y General for Ofc of Legal Counsel DoJ 5224 4:15 pm "How a State Lobbies the Federal Gov't" - Mary Sheehy, Wisconsin State Legislative Director 400 No. Capitol St. Ste 613	<i>RS</i> 2:00 pm "Presenting a Unified Legal Position in the Supreme Court" - Drew S. Days, Solicitor General DoJ 5143 3:30 pm "Lobbying for the Justice Dept." - Maria Olson, Spec. Counsel to AAG for Legis. Affairs DoJ 1145
Dinner/ Evening	Restaurant in Union Station	Restaurant	Restaurant	Restaurant in Georgetown	6:00 pm Intellectual Property Association at []

**MOSCOW WORKSHOP ON EXECUTIVE-LEGISLATIVE RELATIONS
FOR RUSSIAN PRESIDENT'S & PRIME MINISTER'S ADMINISTRATIONS**
Staraya Ploshchad, Moscow - May 29-31, 1995

I. PURPOSES AND BACKGROUND

In 1993 the Lawmaking for Democracy Project began a series of programs on executive-legislative relations designed to provide organizational models and techniques for the Russian President's and Government's senior officials who formulate and implement legislative strategy and lobby on behalf of the executive branch. The 1993 program contributed to the reorganization of the President's Administration in 1994, with the creation of a fully-staffed Authorized Representative of the President to the Federal Assembly and, later, with the formation of a unit for analysis of legislative political forces.

In co-sponsorship with the Russian President's Authorized Representative to the Federal Assembly, Professor Alexander Maximovich Yakovlev, the Project conducted three days of workshops in Moscow for Russian senior staff from the President's and Prime Minister's Administrations. The workshops were intended to convey the overall coordination of legislative policy, communications, and lobbying done by the American President and to open a dialogue on the ways these functions were performed in Russia.

II. PARTICIPANTS

U.S. Participants:

John D. Podesta	Assistant to President Bill Clinton and Staff Secretary, Executive Office of the President
David E. Dreyer	Deputy Assistant to the President for Policy Planning, 1993-95
B. Robert Okun	Assistant to the Republican Leader of the U.S. House of Representatives, 1993-95
Anthony P. Sager	Director, Lawmaking for Democracy Project

Russian Participants:

Sergey Alexandrovich Filatov	Chief of the Administration of President Boris Yeltsin
Alexander Maximovich Yakovlev	Plenipotentiary Representative of the Russian President to the Federal Assembly

Larisa Igoryevna Brycheva	Deputy Director, State-Legal Administration of the Russian President's Administration
Lev Olegovich Ivanov	Assistant to the Plenipotentiary Representative of the Russian President to the Federal Assembly
Andrey Yevgenyevich Sebentsov	Plenipotentiary Representative of the Government of the Russian Federation to the Federal Assembly and Deputy Director of the Apparatus of the Government of the Russian Federation
Lyubov Anatolyevna Ageyeva	Head of the Secretariat of the Plenipotentiary Representative of the Russian President to the Federal Assembly

III. PROGRAM

Overview and Introduction to the Problem of Executive-Legislative Relations in Russia - Sergey Alexandrovich Filatov

President Yeltsin's Chief of Staff opened the program by citing the importance of the workshop's topic, given Russia's history of wrestling for power by the legislative and executive branches and its current political and economic transitions. The fundamental activity of the executive branch is its relationship with the parliament, he said. It has to address how it prepares draft laws, lobbies for them, and does this with "transparency". The President, Prime Minister, and the heads of the legislative chambers devote a lot of attention to legislative issues, and now there are tripartite commissions to resolve differences. They have accumulated experience since the new parliament was formed in January 1994, but there still are many basic laws needed, including one specifying what kind of lobbying activities are permitted.

Background and Workshop Overview - Alexander M. Yakovlev and Anthony P. Sager

Professor Yakovlev summarized Russia's historical experience with legislative failures to control arbitrary rule and favorably cited de Tocqueville's observations about the United States in the nineteenth century. Sager reviewed the purposes and topics of the workshops and invited active dialogue during the presentations.

White House Organization and Executive Branch Development and Implementation of Legislative Policy in the U.S. - John D. Podesta

President Clinton's senior adviser John Podesta described the primary political factors governing the U.S. President's legislative relations: first, the success of a Presidency is seen as the result of his success with Congress, and second, the two-party system governs relations between the two branches.

Podesta reviewed in detail how policy is developed in the White House and how a legislative program to implement that policy is prepared. He covered the process of development of substantive legislative programs, largely within Federal agencies, and the separate process of development of budgets for those programs. He described the sources of policy for national security, economic, domestic, and budgetary issues.

He likewise reviewed how the White House reacts to Congressional legislative initiatives and to Congressional oversight. In choosing a strategy, the executive must take into account, of course, which party holds the majority in each house of Congress, what coalitions can be formed on each issue, how much Presidential and Vice-Presidential time will be needed on each issue, how much support can be expected from outside interest groups, and how the particular issue relates to the overall Presidential program.

In response to questions from Professor Yakovlev, Podesta reviewed the use of Presidential vetoes, veto threats, and Executive Orders; the coordination between the White House and the Cabinet; the inclusion of Congressional staff in executive branch working groups; and the technical presentation of veto messages.

Organization of the Cooperation of the Russian President and Government with the Federal Assembly - Andrey Ye. Sebentsov

The Prime Minister's parliamentary representative Andrey Sebentsov described the Soviet inheritance of the current parliament -- its weak relation to parties and to voters and its tradition of legislative omnipotence -- and the complexities of coordinating Presidential and Governmental policies. In addition, he emphasized the powerful lobbying of individual Ministries for the interests of their sectors of the economy. Formally, the parliamentary representative of the President or Prime Minister introduces draft laws, since these officials have the constitutional right of legislative initiative, pursuant to their respective plans of

legislative activity. However contradictions arise between bills prepared by different Ministries and because of alternative drafts prepared by legislators.

By the Constitution, the annual budget is introduced by the Government, and any bill affecting revenues and expenses can only be introduced with the approval of the Government. It would be helpful, he said, if the State Duma would adopt a rule requiring a fiscal impact study of each bill. The legislature has little power to control the implementation of the budget, which is controlled by the President.

Communicating the President's Message - David E. Dreyer

In the U.S. White House, relations with the press are a central function and involve eight separate offices. All of them are involved in planning legislative programs and strategies. The President's principal vehicle for promoting his legislative program is his annual State of the Union Message to Congress, said Dreyer. He then described in detail the process of its preparation. The Russian participants had numerous questions concerning how it is presented to Congress and how legislators may react to it.

U.S. Executive Branch Lobbying Techniques - B. Robert Okun

Each President brings his own personal style and approach to legislative relations, said Okun, describing the basic styles of the last eight Presidents. He showed how likely votes are tracked and tabulated by White House lobbyists on a vote count sheet, which divides legislators into five categories depending on whether they favor, oppose, are leaning either way, or are undecided about a bill.

He also described the types of tools of persuasion used by the White House, ranging from an agreement to direct federal funds to the legislator's district to an invitation to watch a movie in the White House with the President. Overall, the White House lobbying office pays attention to the feelings and needs of individual legislators, as well as their voting histories, political philosophies, region's interests, and margin of victory in their last election.

In response to a question about the use of bribes, which Okun said was virtually nonexistent, he emphasized that the basic task of a lobbyist is to understand how the particular legislator sees his or her own self-interest, first by gathering relevant information and then responding to those interests.

Role of the President's Representative to the Federal Assembly in the System of Executive-Legislative Relations - Lev O. Ivanov

The President's official representative to the Federal Assembly basically fulfills the President's constitutional powers and tries to advance his interests. He acts in parallel with the State-Legal Administration, which prepares draft laws; the Department for Contact with Deputies, Political Parties, and Social Groups; and the Informational-Analytic Service of the President. As an example, they tried to form a "pro-Presidential" political fraction in the State Duma. There is both a division of functions and coordination of efforts.

Preparation of the President's Annual Legislative Program, Its Priorities, and Its Implementation - Larisa I. Brycheva

State-Legal Administration Deputy Director Brycheva reviewed the legislative process, the executive inputs into it, and the internal coordination in the President's Administration. Because of basic disagreements between the branches, even the Constitutional Court is being asked to decide questions of legislative enactment and signing of laws.

Overall, the President's Administration has sought a more flexible approach to coordinating the legislative priorities of the State Duma and the President. It meets separately with Duma committee chairs and with fraction chairs, and is trying to improve the process of reconciliation of views. Now they are trying to have joint working groups for preparation of draft laws.

Regulation of Lobbyists in the U.S. - John D. Podesta

At the request of the Russian participants, John Podesta summarized the current laws governing disclosure of lobbying activities and registration of lobbyists, frankly described their loopholes and inadequacies, and explained current proposals to strengthen them. He also answered questions about these laws' relations to campaign finance legislation.

Review of the Workshop and Current Issues for the Russian President's Administration and Government - Alexander M. Yakovlev

Professor Yakovlev acknowledged the problems of separating legal and political issues of legislation and of having separate structures to deal with each area. Sometimes political success in forming a legislative coalition can produce a poor legislative result.

Other times, Deputies of varying views can be brought to support good quality legislation. This also has to be seen in the context of a larger political framework, the needs of society in this transitional period and the need for stability of the constitutional framework at this time. Thus, even a harsh opponent of the President might agree regarding the procedure for amending the constitution, so as to have a stable process. In Yakovlev's view, following the constitution is ultimately the most important value for Russia.

IV. CONCLUSION AND FOLLOW-UP

At the concluding workshop session, the U.S. participants reacted to the legislative processes and executive-legislative relations they had heard described. One said that the media and official materials he had previously read did not convey the energy and optimism he perceived amongst the Russian participants. He also noted that in any constitutional system, U.S. or Russian, the power balance of the executive and legislative branches vary over time -- sometimes one or the other is dominant, sometimes there is a vacuum on one side, or there is more cooperation or more adversarial conflict. The important thing is for the system to work in all of these political relationships.

Another U.S. participant pointed out that a strong legislative committee system allows the committee chairs to work out compromises between competing bills even across party lines. Likewise, a committee like the House of Representatives' Committee on Rules can regulate floor debate and amendment, although it can also block important legislation and infringe on the minority's opportunities.

Other U.S. participants recommended the usefulness of expert analysis of financial impacts of bills by executive and legislative branch organizations like the Congressional Budget Office and the Office of Management and Budget, and by private sector expert groups. Likewise, legislators should have up-to-date information on the status of bills. The final point was that, in the end, the most important thing for both the executive and legislative sides to realize is that they must ultimately obey the decision of constitutional issues by their Constitutional Court.

Professor Yakovlev concluded the program by noting how useful and important working sessions, like these workshops, are to practicing politicians and government officials.

Pursuant to the Lawmaking for Democracy Project program and in consultation with U.S. Embassy staff, key Russian officials would travel to Washington, DC, two months later to have discussions with their counterparts "on site" on these same issues. Because the separation of legal policy and political strategy was so apparent in Moscow, and because there appeared to be no integration of communications strategy with these, the Washington program would emphasize the coordination of these three interdependent aspects of legislative relations.

SCHEDULE FOR PRESIDENT YELTSIN'S POLITICAL & LEGISLATIVE ADVISORS
PROGRAM ON EXECUTIVE-LEGISLATIVE RELATIONS IN THE U.S.
WASHINGTON, DC - JULY 22-30, 1995
LAWMAKING FOR DEMOCRACY PROJECT / LAWYERS ALLIANCE FOR WORLD SECURITY

	Monday, July 24	Tuesday, July 25	Wednesday, July 26	Thursday, July 27	Friday, July 28
Breakfast	At hotel	At hotel	At hotel	8:30 Amer. Bar Assoc. NIS Law Cmte Bkfst 740 15 St. 9 fl	At hotel
Morning	10:00 "Planning & Coordinating Legislative Strategy" - Pat Griffin, Assis. to Pres. for Legis. Affairs White House W Wing	10:00 "Office of Management & Budget's Review of Legislation, Role in Veto Process" - James Murr, Assis. Dir., OMB New EOB 11:40 Morton Abramowitz, Pres., Carnegie Endow.	9:00 "Lobbying the Senate" - Steven Richetti, Dir., WH Office of Legis. Affairs White House 107 E. Wing 11:00 "Regulation of Lobbyists" - Thomas Sussman, Ropes & Gray 1001 Penn. Ave. 12 fl. So	10:30 "House Minority Strategy & Relations with the White House" - Tom O'Donnell, Chief of Staff to House Minority Leader Gephardt H-204	9:15 "Lobbying for a Federal Agency" - Lucy Lehman, Cathy Cavalec, Ofc of Legislative Affairs, U.S. Dept of State C St 10:30 Meeting with Brian Atwood, Administrator, Agency for International Development D-5042
Lunch		12-2:00 pm "Russian Politics Leading Up to the Parliamentary & Presidential	Law Firm of Crowell & Moring	12:00 "Enforcing Legislative Rules" - House Parliamentarians Wm. H. Brown, C. Johnson H-209 Capitol	12:00 Heritage Foundation Lunch G. Satarov "Prospects for Russian Democracy" 214 Mass Ave NE
Afternoon	1:30 "WH Legis. Priorities & the 1996 Election" - Jim Brady, State Dem. Chairs 3:00 House Committee on International Relations - Majority & Minority Staff 2170 RHOB 4:30 Senate Foreign Relations Committee - Committee Majority & Senator Dole's Staff S-116	Elections" - G. Satarov Carnegie Endowment, 2400 N St 1:15-2:30 Demonstration of House Information System - Cathy Brickman 660 FHOB 2:45 Congressman Harry Johnston of House Internat'l Relations Cmte 2458 RHOB	1:30 Foundation Meeting w/ Soros, Eurasia, National Endowment for Democracy, NDI, & IRI at Eurasia Fdn 1527 N. Hampshire Ave., NW 4:00 National Security Council Briefing - Steven Pifer Old EOB	3:00 Chrmn Sonny Callahan, House Subcmte on Foreign Operations H-144 3:45 Chrmn Harold Rogers, House Appropriations Subcmte on Commerce, Justice, State Dept. 2468 RHOB 5:00 "White House Communications" - Robert Boorstin, NSC Old EOB	2:00 "Coordinating Administration Legal & Legislative Policies" - Richard Shiffrin, Dep. Assis. Atty Gen. for Legal Policy DOJ 5235 5:00 "Current US-Russia Policy Issues" - Amb.-at-Large James Collins State Dept
Dinner/ Evening	Restaurant, Satarov w/ Z. Brzezinski, Gen. W. Odom. Embassy Row Hotel 2015 Mass. Ave. NW (202) 265-1600 fax 328-7526	6:30 Russian Embassy Reception (Pres. Yeltsin book presentation w/ V. Ilyushin)	Restaurant in Adams-Morgan; Satarov dinner with HIRC Chrmn B. Gilman, Cong. Tom Lantos	Italian restaurant	Maryland Inn, Annapolis (410) 263-2641, fax 268-3813 Sushi & steak restaurant

WASHINGTON PROGRAM ON STRATEGIES AND PRACTICES OF LOBBYING FOR THE PRESIDENT AND FEDERAL AGENCIES

Washington, DC July 22-30, 1995

I. PURPOSE

To give President Yeltsin and Prime Minister Chernomydin's senior advisors responsible for the formation and implementation of legislative strategy a close, first-hand look at the legislative affairs system of the U.S. President and federal agencies, a one-week program was conducted during the State Duma's summer recess. These key advisors would be able to engage in dialogues about overall White House legislative strategies and their implementation.

II. PARTICIPANTS

Georgiy Alexandrovich Satarov	Advisor to President Boris Yeltsin on Relations with the Federal Assembly. Former Director of INDEM Center (political and sociological research and analysis; polling), ROP Center. Ph.D., Technical Sciences, Moscow State Pedagogical Institute.
Andrey Yevgenyevich Sebentsov	Plenipotentiary Representative of the Government of the Russian Federation to the Federal Assembly; First Deputy Head of the Apparatus and Head of the Representation of the Government to the Federal Assembly. Graduate, Moscow Mining Institute.
Larisa Igoryevna Brycheva	Deputy Director of the President's Administration's State-Legal Administration. Former Head of the Apparatus of the Plenipotentiary Representative of the President to the Federal Assembly; Former Head of Department, Commission on Legislative Proposals of the President. Ph.D., Law, Moscow State University.

Because of unexpected personal circumstances, Andrey V. Loginov ¹ was unable to participate as planned.

III. PROGRAM

*Planning and Coordinating Legislative Strategy for the President - Patrick Griffin,
Assistant to the President for Legislative Affairs*

President Clinton's chief advisor on legislative affairs, Pat Griffin, compared his role with that of Georgiy Satarov, his Russian counterpart. Unlike the situation in Moscow, Griffin is responsible for both political and policy issues, the latter including both legal and budgetary policy. Now that the President's party is in the minority in both houses of Congress, the White House has more of a reactive role, trying to support the Democratic leadership in Congress. He himself tries to keep above the daily battles and think about strategic issues.

In response to questions, Griffin explained whom he normally works with in the structure of the White House and with the Cabinet Secretaries and Congressional leadership. He described the process of evaluation of legislation for possible veto action, and who takes part in that decision. He also described how the White House coordinates the Legislative Affairs offices of the federal agencies. As a new President, the Administration initially had too many legislative goals, but these were eventually sorted out by the budget process. And, he noted, even if there were Democratic Party majorities, the Congress would alter legislation proposed by the President.

Satarov answered Griffin's questions regarding who does lobbying in Russia and how powerful they are. They compared the circumstances when vetoes are used, threatened, or, as in Russia, not able to be used, with recourse to the Constitutional Court instead.

*White House Legislative Priorities and the 1996 Election from Local Democratic
Parties' Perspectives - James Brady, Executive Director, and Ann Fishman,
Program Director, Association of Democratic Party State Chairs*

Jim Brady and Ann Fishman described the efforts of state party officials to balance

¹ Head of the Presidential Administration's Department for Interaction with Political Parties, Public Associations, and Factions and Deputies of the Chambers of the Federal Assembly. Ph.D., History, Moscow State University.

their support for the President and of all sectors of the Democratic Party in Congress, and to balance the sometimes conflicting interest of these national actors. The Russians actively questioned them about how the national and state parties influence candidates' positions, where they get their funds, which economic interests support each party, and how campaign expenditures are regulated.

Office of Management and Budget's Review of Legislation and Role in the Veto

Process - James Murr, Assistant Director, Office of Management and Budget

OMB's role in reviewing draft legislation begins with Presidential and federal agency drafts and Congressional subcommittee bills, and extends through evaluation of enrolled bills for vetoing or signing. OMB's Legislative Reference Division Director Jim Murr explained the review process within OMB and within the executive branch, including the reasons OMB may have for recommending that a bill be vetoed. He also responded to the participants' questions about the legislative authorization and appropriations processes.

Approaches to Lobbying the Senate for the White House - Steven Richetti, Director of Office of Legislative Affairs, Executive Office of the President

Steve Richetti described with great candor and in detail the political function of his Office, which is responsible for White House relations with the Senate. Its basic functions are to balance the interests of the executive branch with those of Democratic members of the Senate, and to coordinate the federal agencies' efforts. Depending on the politics between the White House and Congress, compromises which permit legislation to be enacted into law may or may not be reached, since sometimes either side may wish to prolong the conflict for partisan or principled reasons. It is in the President's interest, he believes, for legislation to be enacted, whatever its source. But the closer the 1996 election becomes, the more tolerable will be conflicts between the branches.

In Richetti's view, it strengthens the President when he draws strong lines, and this added strength can help him in negotiations with the opposition-controlled Congress. This need for a strong image of the President must be balanced with the public's desire for legislative results, which are perceived as evidence that the President is an effective leader.

There are similar complexities in the President's relations with his federal agency heads, since strong officials affect the public's perception of what the President stands for,

but are harder to coordinate and bring to a consensus. If the intra-executive branch negotiations can produce consensus on an issue, then it can be sought with fellow party-members in Congress, and finally in negotiations with the opposite party in Congress.

The Russians were very interested in Richetti's personal access to other Administration officials and to Senators, and in his background, the experience that allows him to be effective in his job. They were also interested in the steps of achieving consensus within the executive branch, a sore point in Moscow, and how the President has personal contacts with legislators. Richetti emphasized that the White House's public relations effort is not just an add-on, but that its political strategy consists of all three: substantive policy, legislative program, and communications strategy.

Regulation of Lobbyists and Lobbying Activities - Thomas Sussman, Ropes & Gray

As a private lobbyist for business interests in regard to legislation to reform the lobbying registration laws, Tom Sussman described the organization of a typical lobbying campaign, whether on behalf of business, environment, or consumer groups, or a government agency. Sussman described the current federal laws governing lobbying activities by private persons, organizations, and public officials, and explained the requirements and inadequacies of current lobbying disclosure laws. The purpose of these laws, he said, was to balance the public's constitutional right to petition the government for redress of grievances with the policy goal of preventing Members of Congress from being "bought". The pending Senate reform bill, he contended, was an improvement in the disclosure it would require. The Russian Government's draft law, which Sussman had reviewed, was in his view better than current U.S. law.

*Congressional Minority Party Strategies and Relations with the White House - Joy Drucker, Foreign Policy Aide to House Minority Leader Richard Gephardt*²

House Democratic Minority Leader's staff aide Joy Drucker explained the daily contacts between the chiefs of staff of the Minority Leader and the President, and the direct contacts between the President and Minority Leader, aimed at coordinating their policies and

² Tom O'Donnell, Chief of Staff for the Minority Leader, was unable to do the scheduled briefing because of a last-minute conflict.

alerting each other to possible conflicts. In response to questions, she described the structure of the Democratic Party in the House, how often its leadership and caucuses meet, and the resources and assistance the leadership can provide to caucus members.

*Enforcing Legislative Procedural Rules - Wm. Holmes Brown, former
Parliamentarian, and Charles Johnson, Parliamentarian of the House of
Representatives*

In a luncheon discussion in the House Members' Dining Room, the present and past House Parliamentarians and the Russians compared rules of the House and the State Duma, and commented on their enforcement.

*White House Communications Planning and Implementation - Robert Boorstin,
Director of Communications, National Security Council*

Presidential foreign policy and national security speech writer Bob Boorstin summarized the basic principles of a communications strategy. Unlike the press secretary's functions, which are reactive, the communications staff formulates the message the Administration wants the public to hear through the mass media. As policy is being developed within the Administration, communications specialists do research and advise the policy planners how to describe the policy so as to get public support. The message is then conveyed by the President, his wife, the Vice-President, and Cabinet officials in speeches, events, and activities. In a nutshell, the message should be simple, consistently repeated, and illustrated by pictures, preferably on television.

As the Russians noted, they do not divide their public relations work into active and reactive components, and have problem conveying their programs, especially from their President.

*Lobbying for a Federal Agency - Lucy Lehmann and Catherine Cavalec, Office of
Legislative Affairs, U.S. Department of State*

Deputy Assistant Secretary of State Lucy Lehmann described the breadth of her Office's work with the Congress. It includes all treaties, aid, appointments, and military matters -- in short, any foreign policy issue. All State Department Bureaus conduct their legislative relations through her Office. It works with the Vice-President and key Members of Congress.

The participants questioned her about the role of the State Department in connection with foreign travel by Members, in view of the frequent travel of Russian State Duma Deputies.

Coordinating Administration Legal and Legislative Policies - Richard Shiffrin, Deputy Assistant Attorney General, and Pamela Harris, Attorney Advisor, Office of Legal Counsel, U.S. Department of Justice

Because of the frequency of constitutional questions arising in the course of legislative activity in Russia, the participants were very interested in comparing their experience to that of the principal office for identifying and evaluating constitutional issues in the U.S. Government, the Justice Department's Office of Legal Counsel. Dep. Assis. Attorney General Richard Shiffrin explained the issues his Office primarily looks for -- problems of separation of powers, executive-legislative relations, Presidential authority in foreign affairs and as Commander-in-Chief. Likewise, he reviewed the range of responses by the executive branch to constitutionally questionable legislation: "It's unconstitutional"; "It raises serious constitutional doubts"; and "If passed it will be recommended to the President to veto it".

Demonstration and Explanation of House Information System - Cathy Brickman, House Information Resources

To demonstrate the completeness and timeliness of information available to all Members of the House of Representatives, the House Information System was shown and explained to the participants.

Discussion of Foreign Policy Issues and Russian Domestic Political Issues; Speeches

The week-long program included substantive policy discussions with Majority Staff of the Senate Foreign Relations Committee (Randy Schueneman and Steven Biegun); Congressman Harry Johnston of the House International Affairs Committee; Chairman Sonny Callahan, Subcommittee on Foreign Operations of the House Appropriations Committee; Chairman Harold Rogers of the Subcommittee on Commerce, Justice, and the State Department of the House Appropriations Committee; Majority and Minority Staff of the House International Relations Committee (Mark Gage, Chris Kojm, Martin Sletsinger); Agency for International Development Administrator Brian Atwood and AID senior staff;

Ambassador-at-Large designate James Collins at the State Department; and Steven Pifer of the National Security Council staff.

In addition, Georgiy Satarov had dinner discussions (arranged by former Congressman Don Bonker) with Zbigniew Brzezinski, Gen. William Odom, House International Relations Committee Chair Benjamin Gilman, Congressman Tom Lantos.

Further, Georgiy Satarov gave luncheon addresses on Russian domestic politics in the run-up to the parliamentary elections, and responded to follow-up questions, before large audiences at the Carnegie Endowment for International Peace and at the Heritage Foundation. The participants also made a luncheon presentation at the law firm of Crowell & Moring and had a dialogue with funders from the Eurasia Foundation, Soros Foundation, National Endowment for Democracy, and International Republican Institute on directions for development of civil society in Russia.

Cultural Activities

After the week-long substantive program, the participants traveled to Annapolis, where they visited the U.S. Naval Academy, and the Eastern Shore of Maryland, where they rode bicycles in a small village.

IV. CONCLUSION, EVALUATION, AND FOLLOW-UP

All three program participants reported that it was extremely interesting and useful. During one discussion, following a detailed description of how the House minority leadership works to get votes, participant Satarov commented, "The more I speak with you people, the more I feel how poorly I do my job, since we could have done more in advance to learn the voting records of Deputies, organize people to send them letters, motivate special interest groups, for instance, in regard to the Law on Election of Deputies of the State Duma".

Their copious notes of the discussions also demonstrated the value of the program's discussions to the participants. In response to questions from Steven Richetti and Richard Shiffrin about the value of the discussions, Satarov in both instances pointed to his notes and said, "You can see the places where I have drawn boxes around points that I want to remember and apply, and mention to President Yeltsin when I get back."

As for continuation of the program, Project Director Sager and Satarov discussed the

possibility of an internship in a U.S. state governor's legislative affairs office for an English-speaking member of the President's Administration.

8f.usiareps.d95



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FOR
WORLD
SECURITY**

LAWMAKING FOR DEMOCRACY PROJECT
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December 10, 1996

Monica O'Keefe
USIS Moscow
Fax (095) 255-9766

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Re: Possible Moscow Workshop on Executive-Legislative Relations

Dear Monica:

Based on my discussions with Vladimir Razmustov last month, his boss Georgiy Satarov believes that a further program on executive-legislative relations would be useful.

According to him, it should be in Moscow, be relatively brief (i.e., 1½ days), and include the principal persons who plan and implement legislative policy for the Russian President and Government. From the U.S. side it should include present or recent White House senior staff who could address issues of interest to the Russians (e.g., Chief of Staff Leon Panetta after he leaves office, former Assistant to the President for Legislative Affairs Patrick Griffin or current Assistant Doug Sosnik, and a communications strategy person).

The program format should be a truly two-way round-table exchange of views and experiences, since the time for one-sided presentations has long passed, the Russian President's Administration and Government have accumulated considerable experience in the last three years, and nearly half of the relevant Russian participants have been in our programs during this period.

The topics should be:

- Legislative strategies in the context of opposition majorities in the legislature
- Interaction of legislative and electoral strategies (including early/midterm elections)
- Management and delegation of responsibility within the Administration
- Incorporating communications policy in political and legal policy-making
- Periodic self-evaluation of successes and failures in strategy and tactics as a tool in policy planning.

As you probably know, this would be a continuation of programs we

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Monica O'Keefe
December 10, 1996
Page 2

began three years ago, when the structure for legislative relations in the Russian executive branch consisted solely of one person, the President's "Authorized Representative to the Supreme Soviet". This was Anatoliy Sliva, then Deputy Director of the Administration's State-Legal Administration, who was in our December, 1993, program in Washington. He and his staff returned to Moscow to present a detailed report on the structures and functions for legislative relations in the U.S. federal government. In 1995 we did a workshop in Moscow in May with U.S. White House and Russian presidential staff participating and then a week of meetings for G. Satarov, A. Sebentsov, and L. Brycheva with their U.S. counterparts in DC in July. They reported on these to Yeltsin and then-chief of staff Filatov. Yeltsin's Administration grew and was restructured under Filatov, then shrunken and restructured by Chubais, with a weekly meeting of senior staff involved in legislative affairs. (See attached seating chart.)

This proposed program is intended to stimulate thinking about some of the obvious organizational and policy problems on the Russian side: over dependency on the Chief of Staff with resulting disorganization or inertia in the Administration, reacting to opposition moves without an overall strategy, and inadequate communications strategy.

As with our other programs in this series, it would be done on a "staff-to-staff" basis, with no public or press.

When you and Political Section staff meet with Satarov about this, it would be helpful to get his amendments or suggestions about the proposed topic list, above; how to include the appropriate staff without any turf problems; and possibly how to include Chubais given the demands on his time (e.g., at a concluding session for recommendations). If you then decide this should happen, we would also need to know the dates they could do it and who would be our co-sponsor/contact (last time it was the Parliamentary Representative's office).

We have sufficient funds in the existing USIA grant and from private foundation sources to cover three persons and myself going to Moscow to do this. We could do it as soon as the Russians felt it was feasible. The only logistic requirements on their side would be providing a place and simultaneous interpreters. If the U.S. participants wanted to stay in Moscow an extra day to see the sights, we could help them with that.

If we can help you any further in developing this, please let me know.

Sincerely,



Anthony P. Sager
Director
Lawmaking for Democracy

cc: Kathy Wood

30.1210oke



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January 14, 1997

John D. Podesta,
Deputy Chief of Staff
Executive Office of the President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

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Alex Sleser
Administrator

Dear John:

Congrats and best wishes for successes *only* in your new job!

Yeltsin's Administration is again interested in having senior staff discussions in Moscow on executive-legislative relations. Would you be kind enough to ask Leon Panetta if he would be interested in going to Moscow for this, after he has had some time to relax with his family?

The Russian Executive Branch now has a more developed system for forming and implementing legislative policy, based partly on the program you presented in Moscow. Enclosed is a chart of Chief of Staff Chubais' weekly legislative policy meeting, which is the main coordinating vehicle.

Their Presidential Administration believes it would be useful to them to have round-table discussions focusing on (1) legislative strategies in the context of divided government and (2) management of legislative policy in view of their problems of internal coordination and delegation of authority, especially with Yeltsin absent from the Kremlin.

This would involve a day and a half of discussions, plus any other time desired in Moscow. Funding is from USIA and the MacArthur Foundation.

I'll give you a call about this. Once again, all the best for 1997.

Sincerely,

Anthony P. Sager
Director
Lawmaking for Democracy

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ADMINISTRATION OF THE PRESIDENT OF THE RUSSIAN FEDERATION WEEKLY MEETING ON LEGISLATIVE STRATEGY & TACTICS

MONDAYS AT 5:00 P.M.

Chair: Anatoliy Chubais, Chief of Staff,
Administration of the President (AP)

replaced by
Valentin Yermashov
in late March

Georgiy A. Satarov*,
Advisor to President for
Legislation & Policy

Maksim Boyko,
Deputy Chief of Staff, AP

Anatoliy Ya. Sliva*,
Plenipotentiary
Representative of the
President to the Federation
Council

Andrey Loginov, Head of
Department for Relations
with Federal Assembly &
Non-Governmental
Organizations, AP

Aleksandr A. Kotenkov*,
Plenipotentiary
Representative of the
President to the State
Duma

Mikhail Krasnov,
Advisor to President for
Legal Issues

Ignatiev, Advisor to
President for Economic
Issues

Ruslan Orekhov, Head of
State-Legal Administration
(GPU), AP

Designated Representative
of Ministry of Justice

Larisa I. Brycheva*,
Deputy Head of State-
Legal Administration
(GPU), AP

Samuilov, Head of
Department for Territorial
Issues, AP

Andrey Ye. Sebcntsov*,
Deputy Chairman of
Apparat of RF
Government [Director of
Government's Legislative
Affairs]

Designated Representative
of Aleksandr Kazakov,
Deputy Chief of Staff, AP

* Participated in LAWS' Lawmaking for Democracy Project programs.

Note: If Chief of Staff Chubais is unable to attend, the meeting is held on Tuesdays at 2:00 p.m.

November 1996

obj. rflobby.n.96

Came to
Washington
in Dec. 1993
under this
grant



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LAWMAKING FOR DEMOCRACY PROJECT
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March 27, 1997

Hon. Leon E. Panetta
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Carmel Valley, CA 93924

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Re: Moscow Workshop for President Yeltsin's Administration

Dear Mr. Panetta:

John Podesta may have mentioned to you that President Yeltsin's Administration has asked that we organize a workshop in Moscow for their Administration's senior staff, as part of a continuing program on executive-legislative relations which my organization has been conducting with USIA and MacArthur Foundation support since 1994.

John took part in a similar seminar in Moscow in May, 1995. Based on these and their own intense political experiences, the Russian President's Administration and Government now have a fairly developed system for forming and implementing legislative strategy.

Would you be interested in taking part in such a workshop in Moscow during May or June? It would be particularly valuable to the Russian President's Administration in view of President Yeltsin's return to health and active leadership, and his appointment of a new Chief of Staff just two weeks ago.

Valentin B. Yumashev, appointed Chief of Staff following Anatoliy B. Chubais' move to First Deputy Prime Minister, is a 39 year old professional journalist. He has been a newspaper and magazine writer, general director of a publishing house, co-author of the President's memoirs, publicist in the 1996 presidential campaign, and Presidential media advisor since last August. He is in charge of senior advisors who have strong political and personal skills. He is responsible for directing a large policy-making apparatus.

President Yeltsin's senior political advisor has asked us directly, and through the American Embassy, for a workshop on legislative relations and organization of Presidential staff. This would involve a day and a half or two of round-table discussions, plus any other time you desired in Moscow (and/or St. Petersburg).

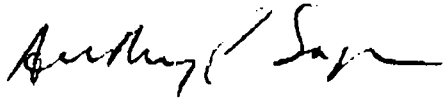
Please let me know if this is at all possible for you, and if so, what are

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Hon. Leon E. Panetta
March 27, 1997
Page 2

potential travel dates. If you have any questions regarding the program, including the possibility of a family member accompanying you, please contact me at (617) 868-1880.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony P. Sager", with a stylized flourish at the end.

Anthony P. Sager
Director
Lawmaking for Democracy

P.S. Enclosed for your information are Annual Reports and other background information on the Lawyers Alliance for World Security and Lawmaking for Democracy Project.

31.0327pan

F

To: Kathy Wood
From: Anthony P. Sager *AS*
Subject: New Head of Russian President's Administration
Date: April 2, 1997

LAWS/LFD
MEMORANDUM

Valentin Yumashev, the new Chief of Staff for Yeltsin's Administration, is a journalist with an appalling lack of political and managerial experience, a point which I did not state explicitly but left "between the lines" in my letter to Panetta. This is why getting Panetta -- and therefore the attention and participation of Yumashev -- is so important. The workshop would be a resource for Yumashev in his new responsibilities, although formally on executive-legislative relations.

Enclosed for your Russian-reading colleagues is biodata on Yumashev. I summarized his professional record in the Panetta letter. *Kommersant-Daily*, Moscow's most pragmatic newspaper, said this about Yumashev on March 11: "The strong sides of Yumashev are his close acquaintance with the President's daughter, Tatiana Dyachenko, ... and his long personal acquaintance with Boris Yeltsin. His weak sides are his lack of experience as leader of a populous bureaucratic structure..., his lousy relations with the many highly placed staff members of the Kremlin apparatus, and his lack of any special desire to occupy the exceptionally politically dangerous and therefore shaky armchair of the Chief of Staff of the President's Administration." *Segodnya* covered the appointment under the headline "Strictly a Family Appointment".

My prediction is that Yumashev will stay in the position only 6-8 months. But this is a crucial time for Yeltsin and Chubais to get executive branch and economy invigorated. Notwithstanding new blood in the Government, the President's Administration will remain the source of political will, control functions, and political direction, particularly as the opposition Duma reacts to Government economic initiatives.

So it would be very helpful to have Panetta participate.

31.0402woo



Office of Citizen Exchanges

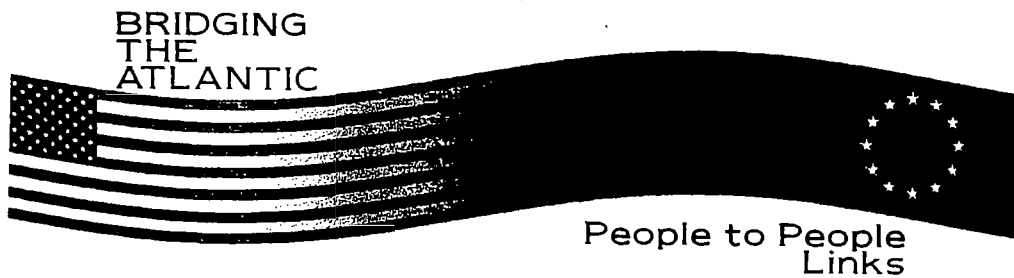
UNITED STATES INFORMATION AGENCY
WASHINGTON, D.C. 20547

4-11-97

Sandy -

Here's the NTA meeting's agenda
from today. Hell, Martha + Ben
Huffy will represent USIA
Monday in the EVC at the Dutch
Embassy. Onward and upward!

Paul



MAY 5-6, 1997
WASHINGTON, D.C.

April 11, 1997
Preparation Meeting for April 14, 1997 DVC
(9:30 AM
Dutch Embassy
Linnean Ave., NW)

AGENDA

- I. Overview:
 - A. 8:45 AM conference call for government to government discussion of logistics
 - B. 9:30 AM DVC begins with opening (Dan Hamilton)
 - C. Civil Society (David Dorn, Pen Agnew)
Education, Culture and Youth (Mike McCarry and Dell Pendergrast)
Electronic Exchange (John Van Oudenaren, Carol Ludwig)
Business (Jim Foster)
- II. Reports from each group:
 - A. Where the group stands and what will be discussed at the DVC
 - B. **APRIL 17, 1997** is due date for one pager from each Working Group
- III. Participation Lists and Responses
 - A. Christine Elder
- IV. Looking Toward the Conference:
 - A. How does each Working Group want their Break-out Sessions to look (Speakers, moderators, etc.)

ST

4/23/97

Thought that you
might be interested.
Good luck!

Best
Bell



Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

FAX TRANSMISSION COVER

DATE April 22 97
TO Bill Ruckelshaus, PL-619-4370

FROM

~~Pamela Matthey~~ *Brian Dooley*
Public Citizen
Ph: (202) 588-1000
Fax: (202) 588-7799

FAX #

619 6988

COMMENTS

INFO ON US-FUNDS

UNETHICAL HIV EXPERIMENTS

Public Citizen
page 2

The health experts including Public Citizen, Wilbert Jordan, M.D., MPH, Chairman of the Black Los Angeles AIDS Consortium, Michael Grodin, M.D. and George Annas, J.D., MPH of Boston University's Health Law Department and George Silver, M.D. of Yale School of Medicine have appealed to Secretary of Health and Human Services Donna Shalala to order the researchers to provide the women in the experiments with AZT immediately and save the infants' lives. "The research violates at least four of the ten principles of the Nuremberg Code," said the letter. They also stated that the experiments may violate the Department's regulations on human research and demanded an investigation by the Department's Office of the Inspector General.

Public Citizen is a non-profit, member-supported, consumer advocacy organization founded by Ralph Nader in 1971. Public Citizen fights for safe foods, drugs and medical devices; for greater consumer control over personal health decisions; and for universal access to quality health care.

#

NO. OF PAGES, INCLUDING COVER SHEET _____

Ralph Nader, Founder

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The dangerous double standard being practiced here is underscored by the fact that both of the U.S.-funded studies being conducted in this country provide AZT or other known effective anti-HIV drugs to *all* women, while only one of the 16 studies in the developing world provides AZT to all study groups. Providing AZT prophylaxis to pregnant, HIV-infected women in research studies in developing countries is clearly feasible; six developing country studies other than the one mentioned above provide AZT to some (but not all) of the women in the studies. In each of these six studies, one group of women is given a placebo instead of AZT.

In essence, the U.S.-funded researchers are conducting experiments abroad that would never pass ethical muster in the U.S. For your department to maintain a double standard in which it funds studies that on the one hand routinely provide life-saving drugs to Americans, while on the other deny these drugs to thousands of citizens of developing countries, conveys to the international community the impression that the U.S. government places less value on the lives of non-Americans.

Many people will hear in these experiments echoes of the notorious Tuskegee syphilis study, in which poor, rural African-American men were denied effective treatment for syphilis for decades so that researchers could describe how the untreated disease progressed in African-Americans. This time, the people of color affected are babies from Africa, Asia and the Caribbean, many hundreds of whom will die unnecessarily in the course of this unethical, exploitative research.

Thus, even as the administration moves toward offering a belated apology for the atrocity of Tuskegee,² it is perpetrating a new African-Asian-Caribbean Tuskegee in which many more people will die.

These experiments are in clear violation of all of the major international, ethical guidelines. The World Medical Association's 1975 Declaration of Helsinki states unequivocally that "In any medical study, every patient—including those of a control group, if any—should be assured of the best proven diagnostic and therapeutic method." It also makes clear that the guidelines are for "physicians all over the world."³ In addition, the research violates at least four of the ten principles of the Nuremberg

² Baker P, Fletcher MA. Binding an untreated wound: Clinton to apologize to blacks victimized in Tuskegee Syphilis Study. *Washington Post*, April 9, 1997, p. A1.

³ World Medical Association Declaration of Helsinki: recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, 1964 and revised by the 29th World Medical Assembly, Tokyo, 1975, the 35th World Medical Assembly, Venice, 1983 and the 41st World Medical Assembly, Hong Kong, 1989.

code (see below).⁴ It is also wholly inconsistent with the more recent International Ethical Guidelines for Biomedical Research Involving Human Subjects, which were specifically designed to address ethical issues pertaining to studies in developing countries.⁵ Guideline 15 is directly applicable to the situation here:

An external sponsoring agency should submit the research protocol to ethical and scientific review according to the standards of the country of the sponsoring agency, and *the ethical standards applied should be no less exacting than they would be in the case of research carried out in [the sponsoring] country.* [Emphasis added.]

Indeed, we would argue that ethical safeguards in developing countries should be at least as stringent as in the industrialized world, as people in developing countries are likely to be more vulnerable. Instead, in their zeal to conduct this research, the researchers, using federal government funds, have chosen to ignore these standards of ethical conduct accepted the world over and have sunk to standards below those acceptable in their home countries.

In our view, the research is not only blatantly unethical, but also violates U.S. federal regulations that require that Institutional Review Boards ensure that:

Risks to subjects are minimized...by using procedures which are consistent with sound research design and *which do not unnecessarily expose subjects to risk.*⁶ [Emphasis added.]

The regulation is also clear that it also applies to "research conducted, supported or otherwise subject to regulation by the Federal Government outside the United States."⁷ We request that you immediately initiate an investigation by the HHS Office of the Inspector General into possible violations of federal law.

⁴ Trials of war criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2 Washington, D.C.: U.S. Government Printing Office, 1949.

⁵ Council for International Organizations of Medical Sciences, World Health Organization. International Ethical Guidelines for Biomedical Research Involving Human Subjects, 1992.

⁶ 45 CFR 46.111(a)(1).

⁷ 45 CFR 46.101(9).

The scientific basis for treating HIV-infected pregnant women with AZT

It is projected that by the year 2000 six million pregnant women will be infected with HIV, primarily in Asia and sub-Saharan Africa.⁸ In the absence of prophylaxis, transmission from HIV-infected mother to infant occurs in between 13% and 48% of pregnancies, with rates in developing countries typically being higher than in industrialized countries.⁹ In the U.S., 933 AIDS cases involving mother-to-infant transmission were reported in 1994, and, at least in the period prior to Protocol 076, an estimated 1,000 to 2,000 HIV infections via this route were estimated to occur annually.¹⁰

The single most important advance in the prevention of HIV transmission from mother to infant has been the AZT regimen demonstrated to be effective in Protocol 076. Beginning in April 1991, researchers at a large number of sites in the U.S. and France conducted a randomized, double-blind, placebo-controlled trial in which the treatment group received oral AZT beginning at 14-34 weeks of pregnancy and intravenous AZT during labor. The newborns received oral AZT beginning shortly after birth and continuing for six weeks. In order to reduce the likelihood that subjects in one of the two study arms were benefiting or being harmed compared to those in the other study arm, a Data and Safety Monitoring Board was constituted and was scheduled to review the interim results on three occasions. At the first interim analysis, in December 1993, the findings were so striking that the study was stopped and AZT prophylaxis was offered to all women and infants still in the study.¹¹ On June 6-7, 1994, the Public Health Service convened a meeting to discuss the ramifications of Protocol 076 and concluded that the full Protocol 076 regimen should be recommended to all HIV-positive pregnant women without significant prior exposure to AZT, and should be considered for other women on a case-by-case basis.¹² Providing AZT thus became the standard of care for HIV-infected pregnant women.

⁸ Scarlatti G. Paediatric HIV infection. *Lancet* 1996;348:863-868.

⁹ Dabis F, Mselatti P, Dunn D, et al. Estimating the rate of mother-to-child transmission of HIV. Report of a workshop on methodological issues, Ghent (Belgium), 17-20 February, 1992. The Working Group on Mother-to-Child Transmission of HIV. *AIDS* 1993;7:1139-1148.

¹⁰ Centers for Disease Control and Prevention. National HIV serosurveillance summary: results through 1992. Vol. 3 Atlanta: U.S. Department of Health and Human Services, Public Health Service, 1994.

¹¹ Connor, EM, op. cit.

¹² Centers for Disease Control and Prevention. Recommendations of the U.S. Public Health Service Task Force on the use of zidovudine to reduce perinatal transmission of human immunodeficiency virus. *Morbidity and Mortality Weekly Report* 1994;43(RR-11):1-20.

In November 1996, the Protocol 076 researchers published updated data describing their findings.¹³ In the placebo group, 22.6% of the infants of the HIV-infected mothers had become infected with HIV, compared to only 7.6% of those treated with AZT, a reduction of approximately two-thirds. The provision of AZT to HIV-positive pregnant women is still the only intervention for any group at risk for HIV to be proved effective in reducing the number of new HIV infections in a randomized, controlled trial. The impact on actual clinical outcomes in the U.S. has been dramatic. Three recent reports document decreases in HIV transmission from HIV-infected mother to infant of 50% or more.^{14,15,16}

While the industrialized world celebrated these landmark findings, it quickly became clear that the vast majority of HIV-infected women would never receive this potentially life-saving intervention due to both the exorbitant cost of the drug and logistical difficulties in administering and assuring adherence with the complex regimen.

We are, therefore, not opposed to research that modifies the regimen provided in Protocol 076 in order to identify a simpler, less expensive, similarly effective or more cost-effective intervention; we do object to studies in which, after the Protocol 076 results were available, some or all women are only given placebos or regimens without support from randomized, placebo-controlled trials, and are not given effective prophylaxis.

However, the researchers involved in these experiments have exploited the inadequacies of the health care systems in developing countries to conduct research they would never even consider in the U.S. We have obtained a table prepared in

¹³ Sperling RS, Shapiro DE, Coombs RW, et al. Maternal viral load, zidovudine treatment, and the risk of transmission of human immunodeficiency virus type 1 from mother to infant. *New England Journal of Medicine* 1996;335:1621-1629.

¹⁴ Fiscus SA, Adimora AA, Schoenbach VJ, et al. Perinatal HIV infection and the effect of zidovudine therapy on transmission in rural and urban counties. *Journal of the American Medical Association* 1996;275:1483-1488.

¹⁵ Cooper E, Diaz C, Pitt J, et al. Impact of ACTG 076: use of zidovudine during pregnancy and changes in the rate of HIV vertical transmission. In: Program and Abstracts of the Third Conference on Retroviruses and Opportunistic Infections, Washington, D.C., January 28-February 1, 1996. Washington, D.C.: Infectious Diseases Society of America, 1996:57.

¹⁶ Simonds RJ, Nesheim J, Matheson P, et al. Declining mother to child HIV transmission following perinatal ZDV recommendations. Presented at the 11th International Conference on AIDS, Vancouver, Canada, July 7-12, 1996.

approximately January 1997 by Dr. Joseph Saba of the United Nations AIDS program that summarizes studies of mother-to-infant transmission which have either begun since the completion of the historic Protocol 076 trial or are about to begin (see attached). Other information about these studies was obtained from the Pediatric and Family Studies Section, Epidemiology Branch, Division of HIV/AIDS Prevention, CDC. The studies evaluate a variety of potential interventions: AZT (or other similar anti-HIV drugs), usually in regimens less expensive or complex than in Protocol 076; nevirapine, another anti-HIV drug; Vitamin A; vaginal washes; and HIV immune globulin (a form of immune therapy). The studies involving AZT generally explore the optimal dose and timing of AZT administration. A total of 17 studies appear in the table, two of which are in the U.S. The remainder are in developing countries, primarily in Africa: three studies each in Cote d'Ivoire and Uganda, two studies each in Thailand, Tanzania and South Africa, and one study each in Ethiopia, Burkina Faso, Malawi, Zimbabwe, Kenya, and the Dominican Republic. Two studies are occurring at more than one site. We are also aware of an additional study in Malawi that has been completed but is not in the table. This study enrolled 2,094 women in an NIH-funded study of vaginal washing.¹⁷ Of the studies in the table, two have been completed: the NIH-funded study by Johns Hopkins University in Malawi, the data from which are now being analyzed, and the NIH-funded ACTG 185 in the U.S., which was terminated early when the transmission rate from the women, all of whom received AZT, to their infants was about 4.8%, even lower than in the treatment group in Protocol 076.¹⁸

The two studies in the U.S. both provide anti-HIV drugs to all study subjects,¹⁹ as does one of the studies in the developing countries, that conducted by Harvard University in Thailand using NIH funds. This leaves 15 randomized, controlled trials (including the one study not in the table), all in developing countries in which some or all HIV-infected pregnant women are denied effective prophylaxis. Seven of the 15 studies are funded by the NIH and two are funded by the CDC. A total of 9,055 women are enrolled in the nine U.S.-funded studies, 2,903 of whom will receive placebos and 3,780 of whom will receive regimens not proved effective in randomized, controlled trials. The remaining six studies are funded by the ANRS (the French equivalent of the NIH; two studies), the United Nations AIDS program, the University

¹⁷ Biggar RJ, Miotti PG, Taha TE, et al. Perinatal intervention trial in Africa: effect of a birth canal cleansing intervention to prevent HIV transmission. *Lancet* 1996;347:1647-1650.

¹⁸ Brown D. AZT effective in pregnancy with advanced AIDS. *Washington Post*, March 27, 1997, p. A6.

¹⁹ Even though this is listed as a placebo-controlled study, subjects in ACTG 316 receive AZT in a regimen similar to that studied in Protocol 076 or another anti-HIV drug, unless their physician decides it is not indicated. The study examines whether the addition of intrapartum and postpartum nevirapine confers added protection from infection.

of Natal and Department of Health in South Africa, and groups from Denmark and Belgium. In these six studies, in which 5,160 women are enrolled, 1,855 will receive placebos and 1,490 will receive regimens that have not been proved effective.

(In designating whether women in an experimental arm received effective prophylaxis, a placebo or a regimen not proven effective, we made the following assumptions: 1. if AZT was provided in any phase of the study, we classified the study as providing effective prophylaxis; 2. IVIG was considered a regimen not proved effective, rather than a placebo even though the table describes it as a placebo; 3. nevirapine was considered a regimen proved as effective as AZT, even though it is from a different pharmaceutical class from AZT and has not been proved effective in a randomized, controlled trial; and 4. for two studies in the table, the designs of which were not self-evident, we made the following assumptions about study design: for the NIH-sponsored study by Harvard University in Tanzania, we assumed that there would be four study arms: retinol/multivitamin; retinol/placebo; placebo/multivitamin; placebo/placebo. We classified the first three groups as receiving a regimen not proved effective and the fourth as a placebo group. In the Belgian cooperation study in Kenya, we also assumed that the study had four arms: chlorhexidine/azithromycin; chlorhexidine/placebo; placebo/azithromycin; placebo/placebo. Again we classified the first three groups as receiving a regimen not proved effective and the fourth as a placebo group. Each of these four assumptions tends to lead either to underestimations of the number of persons denied effective prophylaxis or to assignment to the not proven effective as opposed to the placebo category, making the calculations conservative.)

It is possible to calculate the number of infants who will unnecessarily become infected with HIV in these unethical studies, assuming that the regimens not yet proved effective are indeed not effective. (This assumption seems reasonable. The only published clinical trial of a prophylactic regimen since Protocol 076, chlorhexidine vaginal washing in Malawi, showed no overall effect on mother-to-infant HIV transmission²⁰ and the recently terminated ACTG 185 showed no effect of HIVIG on such transmission, although the study's statistical power was low.²¹) First, we assumed that in all of the studies the number of subjects in each study arm is equal, even though we understand that in some studies the placebo groups may be larger to increase statistical power. Second, we assumed that the rate of HIV transmission in the absence of any prophylaxis is the same as that in the placebo group in Protocol 076 (22.6%), even though in some studies, particularly in developing countries, the transmission rate is up to twice as high.²² Third, we assumed that the administration of AZT would decrease the rate of HIV transmission to the rate observed in the treatment group in Protocol 076 (7.6%), even though the transmission rate in the terminated Protocol 185 was only 4.8%. These three assumptions lead to estimations of the number of preventable HIV infections that are probably lower than is actually the case. In the 15 studies, a total of 10,028 women will not receive effective prophylaxis such as AZT. Fifteen percent of them (22.6% - 7.6%) will give birth to infants with HIV

²⁰ Biggar RJ, op. cit.

²¹ Brown D, op. cit.

²² Dabis F, op. cit.

infection that could have been prevented by AZT or a similarly effective regimen—a total of 1,504 preventable deaths. Of these, 1,002 will occur in U.S.-funded studies and 502 will occur in those funded by foreign governments or the United Nations AIDS program. Even if only the placebo arms of the studies are considered, a total of 714 preventable HIV infections, 435 of them in U.S.-funded studies, will occur.

It is a violation of basic research ethics to assert that the failure to prevent HIV infection in these studies is somehow justified by the potential for preventing future HIV infections based on data that may be generated in this research. As the World Medical Association has declared: "Concern for the interests of the subject must always prevail over the interests of science and society."²³ In part, this ethical principle was enunciated to prevent the more powerful from using theoretical future gains to place the less powerful at risk in the present. Indeed, the very fact that the subjects of these studies are persons of color from impoverished, mostly post-colonial societies underscores the dangers of such rationalizations.

Clearly, any simpler or less expensive prophylactic regimen that was as effective and safe as that used in Protocol 076 would be rapidly adopted in the industrialized world and while it is true that many of the strategies being tested in these studies are less expensive than that used in Protocol 076, they may still be unaffordable in developing countries. There is, therefore, no guarantee that women and infants in developing countries will even benefit from any knowledge gained from this research. As a recent editorial entitled "Scientific Imperialism" in the *British Medical Journal* proclaimed: "If they won't benefit from the findings, poor people in the developing world shouldn't be used in research."²⁴

Defenders of these studies will no doubt argue that the subjects are being provided the "standard of care" practiced in these developing countries, which is to say regimens that have not been proved effective or no treatment at all. (Of course, this coerces potential subjects to enroll, as outside of the study they stand essentially no chance of obtaining proven effective prophylaxis.) Yet the standard of care in the U.S.—Protocol 076—can be delivered in the research setting in developing countries and is essentially being provided as one of the arms of the only developing country study here that is ethical: Harvard University's NIH-funded study of various regimens of AZT prophylaxis in Thailand. Researchers acquire greater ethical responsibilities when they enroll subjects in studies. As NIH Director Harold Varmus stated at a recent meeting regarding the Alaska needle exchange study, clinical trials funded by the NIH should comply with a higher ethical standard. Instead, many of these studies subscribe to a kind of lowest common denominator ethics in which the abominable state of health

²³ World Medical Association, op. cit.

²⁴ Wilmhurst P. Scientific imperialism. *British Medical Journal* 1997;314:840-841.

care in developing countries is used to justify withholding life-saving interventions.

Incredibly, most of these studies have, to the best of our knowledge, passed ethical review by committees both in the developing country and in the West, providing further proof of the inadequacy of the current review system. We believe that the CDC-funded studies have passed review at the CDC itself, but do not know whether NIH's Office for Protection from Research Risks reviewed the NIH-funded studies. (The University researchers would also have been required to seek the formal approval of the Institutional Review Boards at their own institutions.) These events also demonstrate that the approval of a developing country ethics committee, while essential, is not sufficient to guarantee an ethical study. Developing country committee members, most of whom are likely to be researchers, are usually from social classes higher than the study subjects and may not be able to adequately reflect the subjects' interests. For developing country researchers, involvement in international studies offers obvious benefits in prestige and, perhaps, in salary.

It is true that providing AZT according to Protocol 076 or other similar regimens to all subjects could lower the number of new HIV infections to the point that it may be more difficult to statistically demonstrate differences between the study groups. Indeed, this is the crux of the researchers' conflict of interest: it is the potential for large numbers of infections among women denied AZT that makes the developing countries "preferable" as study sites to industrialized countries where AZT would have to be provided to all HIV-positive pregnant women. The solution to this conflict of interest is not to create a research double-standard; it is to spend the money for larger studies, perhaps at multiple sites in the industrialized or developing worlds, with appropriate informed consent. For example, one study arm could receive AZT and the other AZT and the experimental prophylactic regimen. With the public scrutiny that will accompany these studies, as well as the HIV vaccine studies that may follow, researchers cannot afford to be unethical.

The failure to provide effective prophylaxis to all women in these research studies can also not be explained by the cost of providing AZT in the research setting; after all, both the U.S. studies offer anti-HIV drugs to all subjects and seven of the studies outside the U.S. provide some form of AZT prophylaxis in some study treatment arms. The wholesale cost of the Protocol 076 regimen has been estimated at \$614²⁵ and \$895²⁶ per person. In the context of the hundreds of thousands, if not

²⁵ Gorsky RD, Farnham PG, Straus WL, et al. Preventing perinatal transmission of HIV – costs and effectiveness of a recommended intervention. *Public Health Reports* 1996;111:335-341.

²⁶ Mauskopf JA, Paul JE, Wichman DS, White AD, Tilson HH. Economic impact of treatment of HIV-positive pregnant women and their newborns with zidovudine: implications for HIV screening. *Journal of the American Medical Association* 1996;276:132-138.

millions, of dollars being spent on these studies, this is a modest amount of money. In any event, the manufacturer of AZT has in the past customarily provided the medication for these trials free of charge.

Following World War II, the Nuremberg Code of research conduct was adopted.²⁷ In this 50th year since the commencement of the Nuremberg doctor trials, it is disheartening in the extreme that, at a minimum, four of the ten principles of the Code have been abrogated in this research. (We have not yet obtained the informed consent forms for these studies, and so it is conceivable that additional principles of the code have not been followed and that the studies are therefore even more unethical than we state here. However, no informed consent process can make ethical the withholding of effective prophylaxis.) The violated Nuremberg principles are:

Principle Two: "The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature."

Principle Four: "The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury."

Principle Five: "No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur except, perhaps, in those experiments where the experimental physicians also serve as subjects."

Principle Seven: "Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death."

Is it really your Department's position that these Principles apply to research conducted in the U.S., but that researchers using U.S. taxpayers' money are free to disregard them the moment they leave our shores?

²⁷ Trials of war criminals before the Nuremberg Military Tribunals, op. cit.

We request that you immediately order the researchers in these studies to provide effective prophylaxis to all subjects in these studies and that you pressure the foreign governments who are also funding these studies to do likewise. We also request that you immediately ask the HHS Office of the Inspector General to launch an investigation into how these U.S.-funded studies received ethical approval and into possible violations of federal law. We are confident that you would not wish the reputation of your department to be stained with the blood of foreign infants.

Sincerely,



Peter Lurie, MD, MPH
Research Associate
Public Citizen's Health Research Group



Sidney M. Wolfe, MD
Director
Public Citizen's Health Research Group



Wilbert Jordan, MD, MPH
Director, Oasis Clinic and Aids Program
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Chairman, Black Los Angeles
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George Silver, MD
Emeritus Professor of Medicine
Yale University
School of Medicine

These charts were
prepared by Public
Citizen's Health Research
Group.

Vertical transmission clinical trials

<u>Funding Agency, PI</u>	<u>Sites</u>	<u>Study arm</u>	<u>Prepartum</u>	<u>Intrapartum</u>	<u>Postpartum</u>	<u>Number HIV+ women in group</u>	<u>Status, comments</u>
CDC	Cote d'Ivoire	One	ZDV	ZDV	Nothing	750	Ongoing
		Two	Nothing	Nothing	Nothing	750	
CDC	Thailand	One	ZDV	ZDV	Nothing	196	Ongoing
		Two	Nothing	Nothing	Nothing	196	
UNAIDS	Uganda (2) Tanzania (1) South Africa (2)	One	ZDV/3TC	ZDV/3TC	ZDV/3TC (M/C)	475	Ongoing
		Two	Nothing	ZDV/3TC	ZDV/3TC (M/C)	475	
		Three	Nothing	ZDV/3TC	Nothing	475	
		Four	Nothing	Nothing	Nothing	475	
NIH (Harvard) Mark Lallemand	Thailand	One	ZDV week 28	ZDV	ZDV 6 wks (C)	389	Not started yet No placebo group Arm one ~ 076
		Two	ZDV week 28	ZDV	ZDV 3 days (C)	389	
		Three	ZDV week 36	ZDV	ZDV 6 wks (C)	389	
		Four	ZDV week 36	ZDV	ZDV 3 days (C)	389	
NIH (JHU) Andrea Ruff	Ethiopia	One	ZDV	ZDV	ZDV (M/C)	313	Not started yet
		Two	ZDV	ZDV	Nothing	313	
		Three	Nothing	Nothing	Nothing	313	
NIH (JHU) Brooks Jackson	Uganda	One	Nothing	ZDV	ZDV (C)	400	Not sure if started
		Two	Nothing	NVP	NVP (C)	400	
		Three	Nothing	Nothing	Nothing	400	
ANRS	Cote d'Ivoire Burkina Faso	One	ZDV	ZDV	ZDV (M)	390	"Probably begun"
		Two	Nothing	Nothing	Nothing	390	
ACTG 316	USA	One	+ARV	+ARV/NVP	+ARV/NVP (C)	400	+ARV=as rxd by PMD; stratified random. by ARV
		Two	+ARV	+ARV	+ARV	400	



FAX TRANSMITTAL

DATE:

April 25, 1997

TO:

Sandy Thurman

FAX #:

619-4350

FROM:

Grayson Fowler

6 PAGES INCLUDING COVER SHEET

DRAFT

**REMARKS : SANDY THURMAN
TO: SFAF LEADERSHIP DINNER
DATE: APRIL 24, 1997**

IT IS WONDERFUL TO BE HERE WITH ALL OF YOU TONIGHT.

**AS YOU KNOW, I'M JUST GETTING STARTED MORE OR LESS IN MY JOB
AND I CAN'T THINK OF ANY BETTER PLACE TO BEGIN THAN HERE
WITH THE SAN FRANCISCO AIDS FOUNDATION.**

**INDEED, THE FOUNDATION AND THIS CITY ARE THE VERY EPIITOME
OF "FIRSTS" IN THE FIGHT AGAINST AIDS.**

**IT WAS IN THE FOUNDATION'S CONFERENCE ROOM THAT THE
RYAN WHITE CARE ACT FIRST WAS DRAFTED.**

**IT WAS IN THIS CITY THAT THE FIRST HIV MODEL OF
COMMUNITY CARE WAS ORGANIZED, LATER TO BE COPIED
WORLDWIDE.**

IT WAS THIS CITY THAT FIRST DEVELOPED A PREVENTION CAMPAIGN TARGETED TO REACH GAY YOUTH.

AND SAN FRANCISCO IS THE FIRST CITY TO EFFECTIVELY FORGE AND SUSTAIN PUBLIC PRIVATE PARTNERSHIPS. I KNOW THAT MANY OF THOSE CORPORATE PARTNERS ARE HERE TONIGHT AND I WANT TO PERSONALLY RECOGNIZE THE IMPORTANCE OF YOUR LEADERSHIP AND THANK YOU ON BEHALF OF ALL OF US WHO HAVE SERVED IN COMMUNITY BASED ORGANIZATIONS AROUND THE COUNTRY.

ON A MORE PERSONAL NOTE, I AM HERE TONIGHT BECAUSE I HAVE BEEN HONORED TO WORK WITH PAT CHRISTEN AND HER STAFF IN THE WAR AGAINST AIDS FOR THE PAST 10 YEARS. WHEN I WAS THE EXECUTIVE DIRECTOR OF AID ATLANTA, PAT IMPRESSED ME IMMEDIATELY AS SMART, CAPABLE AND TOTALLY COMMITTED. TODAY SHE CONTINUES TO INSPIRE ME TO THINK MORE CREATIVELY, WORK MORE TENACIOUSLY AND FOCUS MORE EXCLUSIVELY ON THE REAL AND COMPELLING NEEDS OF PEOPLE

LIVING WITH THIS DISEASE. I HOPE TO BORROW HER THICK SKIN AS WELL, AS I MOVE INTO MY NEW ROLE AT THE WHITE HOUSE!

YOU KNOW WE MIGHT NOT HAVE HAD GENERALS LEADING THE FIGHT AGAINST AIDS BUT WE HAVE HAD NO SHORTAGE OF BRAVE AND COMMITTED LEADERS LIKE PAT AND RENEE, LIKE MARTY AND UNIZE AND SO MANY OTHER OUTSTANDING INDIVIDUALS FROM SAN FRANCISCO -- AND POINTS BEYOND -- I AM PROUD TO HAVE HAD THE PRIVILEGE OF WORKING WITH THEM IN THE PAST AND I LOOK FORWARD TO WORKING WITH THEM IN THE FUTURE.

TODAY WE FIND OURSELVES AT WHAT I BELIEVE IS A UNIQUE JUNCTURE IN THIS EPIDEMIC WHILE THE ADVENT OF PROTEASE INHIBITORS AND OTHER SCIENTIFIC ADVANCES GIVE US GREAT REASON FOR HOPE -- WE HAVE MANY CHALLENGES AHEAD OF US --

IN PREVENTION -- SOME OF OUR "JUST SAY NO" APPROACHES TO PREVENTION ARE AS EFFECTIVE IN DECREASING THE TRANSMISSION OF HIV AS "HAVE A NICE DAY" APPROACHES ARE IN

April 21, 1997



The Honorable William Jefferson Clinton
President of the United States of America
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President:

I am writing on behalf of AIDS Action Council, the national voice of over 1400 community-based AIDS service organizations and the people living with HIV/AIDS they serve across the nation, to express our opposition to the recently passed Assisted Suicide Funding Restriction Act (H.R. 1003) and to urge you to veto this ill-conceived legislation.

AIDS Action is dedicated to the development and implementation of effective national initiatives for prevention, care, research and treatment which are responsive to and respectful of the needs of all people living with HIV/AIDS. In that regard, AIDS Action believes that people living with AIDS have a fundamental constitutional right to make individual decisions about how they live with this disease, including their right to freely choose in a dignified and humane way the manner and time of their death and to have the assistance of their physicians and/or other health care professionals in making such decisions. AIDS Action joined as amicus curiae in Compassion in Dying v. Washington State before the Ninth Circuit Court of Appeals and the United States Supreme Court because we believed that the Washington state law that totally banned physician assisted suicide unduly burdened the exercise of that fundamental right. While we believe that states do have significant interests in ensuring that this right is not abused or misused, an absolute ban is unconstitutional, especially given that there are less restrictive alternatives available to a state that would in fact serve these important interests.

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Fax 202 986 1345
Tel 202 986 1300

We oppose H.R. 1003, which, under the guise of "merely restricting" the use of federal funds for assisted suicide, allows the federal government to interfere with the fundamental right of mentally competent, terminally ill individuals to make personal life and death decisions about medical care and treatment. In fact, no federally-funded health care program currently authorizes payment for assisted suicide or anything remotely related. However, by imposing a generic ban on federal funding to all health care programs that in any way address assisted suicide for terminally-ill, mentally competent individuals, this legislation chills discussion, debate, and decision-making in a wholly inappropriate and arbitrary manner.

H.R. 1003 does not merely ban payment for the specific services or medications related to carrying out an assisted suicide, but creates an implied "gag rule" on counseling and/or informing patients of the availability of existing end-stage medical treatment options that under this Act might be considered "assisting" suicide.

While the Act ostensibly permits terminating food/hydration and/or providing pain medication even if it would hasten death, *the latter is permitted only if it is not*

April 21, 1997

Page 2

provided "for the purpose of causing or assisting in causing death". If a health care provider or hospital feared that it could be liable because it could not prove that the purpose of providing pain medication was **not** to hasten death, or that it might be considered "assisting suicide" under this federal law, the provider might not tell the patient about such options or might refuse to comply with the patient's directives, for fear of losing medicaid or other federal funding sources. For example, there are a number of ways to provide end-stage pain relief, some of which are more likely to hasten death. If health care providers are only willing to risk offering pain relief options that they feel are less likely to be seen as "purposely" hastening death, patients might be forced to accept less effective or desirable pain relief options that would merely prolong death until the patient succumbs to organ failure, pneumonia, etc.

Even if a state decided to legalize physician-assisted suicide, or the US Supreme Court decides that mentally competent terminally ill patients have a fundamental constitutional right to the assistance of their physicians in making decisions about assisted suicide, this Act would use the financial power of the federal government to deny patients the ability to exercise their rights. This Act would even undermine existing federal medicaid provisions that require patients be given the opportunity to complete advance directives about medical treatment in the event the patient becomes incompetent. The Assisted Suicide Funding Restriction Act would amend these provisions so a health care provider is not "required" to "inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing ... or assisting in causing, the death of the individual, such as by assisted suicide [or] euthanasia" in these advance directives.

Through this Act, the federal government is explicitly interfering in the sanctity and privacy of the doctor-patient relationship, by placing the health care providers' financial interests squarely in conflict with the rights of the patient to make informed decisions about medical treatment. The implications of setting such a precedent are obvious and frightening. If the federal government can interfere in this manner with regard to individuals' decision-making about end-of-life medical treatments, what is to stop it from interfering with medical decision-making about other health issues, such as abortion?

Lastly, the Act's ban on federal funding does nothing to address the true concerns about assisted suicide, such as ensuring that there are procedural and substantive protections against coercion and other potential abuses of legalized assisted suicide. Such concerns must be addressed through research and public debate that includes input from all affected communities. This Act effectively stifles that debate.

We hope that you will see this legislation for what it is -- a blatant attempt to interfere with the fundamental rights of personal autonomy and individual decision-making of terminally ill, mentally competent individuals. On behalf of AIDS Action Council and people living with AIDS across the nation, I urge you to veto this legislation.

Sincerely,



Daniel Zingale
Executive Director



URGENT -- PLEASE DELIVER IMMEDIATELY!!!
GOVERNMENT AFFAIRS DEPARTMENT
FAX TRANSMISSION

TO: Sandy Thurman, Director, Office of National AIDS Policy

FROM: Aimee Berenson, Director of Government Affairs
(202) 986-1300 ext. 3024

NUMBER OF PAGES: 3

DATE: April 23, 1997

COMMENTS:

Please see the attached letter dated 4/21/97 to the President regarding H.R. 1003, the Assisted Suicide Funding Restriction Act.

AIDS Action is urging the President to veto this ill-conceived legislation.

Please feel free to contact either Daniel Zingale, Executive Director, at ext. 3011 or myself if we can be of any assistance to you in this matter.

1875

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20009

Fax 202 986 1345

Tel 202 986 1300

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Preventing the Spread of AIDS in Youth

Principles of Practice From Intervention Projects

PATRICIA A. WREN, M.P.H., NANCY K. ALZ, Ph.D., KATHY N. GAROVANO, M.A.,
MARC A. ZIMMERMAN, Ph.D., AND KATHY M. WASHENKO, M.P.H.

Purpose: The purpose of this study was to identify the factors that contributed to intervention effectiveness in acquired immunodeficiency syndrome (AIDS) prevention projects targeting youth.

Methods: Eleven AIDS prevention projects funded by the Robert Wood Johnson Foundation whose target populations consisted of at least 60% youth were selected. A blended methodology resulted in quantitative data (from survey responses) from all 11 projects supplemented with qualitative data (i.e., open-ended interviews from in-depth site visits to six projects).

Results: Projects reported using a mean of 11.6 intervention activities (selected from a list of 30). Small group discussions were used by all 11 projects. Small group discussions were rated as one of three most effective activities by 72.7% of the projects that used them. Project staff identified three elements of effective interventions: involvement of peer educators, recognition of the role of family (e.g., parents, teachers), and use of structured settings to gain access to the target population. Of 10 schools, 8 had access to the target population.

Conclusions: The most powerful principles described by project staff for reaching adolescents at risk for human immunodeficiency virus (HIV) transmission include bringing considerable challenges. Opportunity costs associated with using peer educators, gatekeeper support, and structured settings may include limited control of the message, impaired credibility, and failure to reach youth at greatest risk of HIV infection, respectively.

From the Department of Health Behavior and Society, School of Public Health, University of Michigan (P.A.W., N.K.J., K.C., M.A.Z.); and The International AIDS Education and Training Center, Seattle, Washington (K.N.G.). Address reprint requests to Patricia A. Wren, M.P.H., Department of Health Behavior and Health Education, School of Public Health, University of Michigan, 1420 Washington Hospital Drive, Ann Arbor, MI 48109-2029.

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Health educators will do well to consider the advantages and disadvantages of these factors when developing, implementing, and evaluating AIDS prevention programs for youth. *Society for Adolescent Medicine, 1997*

KEY WORDS: HIV/AIDS prevention, adolescents, education, peer educators, structured settings, small group discussions.

In the United States, adolescents are at increasing risk for acquired immunodeficiency syndrome (AIDS) as a result of their sexual and drug use behaviors (1-5). Half of all new infections occur among people under the age of 25 years, and one-third occur among teenagers. AIDS is now the sixth leading cause of death among youth 15-24 years of age and the leading cause of death among 20-24-year-olds (5). In a national probability sample of high school students, 3% reported injecting drugs and 10% having had sexual intercourse; 40% of the latter had had four or more sexual partners (7). Among out-of-school youth, the prevalence of these and other high-risk behaviors (e.g., exchanging sex for money or drugs) is even higher (8).

These data indicate that primary prevention efforts to halt the spread of human immunodeficiency virus (HIV) are essential. While some contract HIV during adolescence, many more develop patterns of high-risk behavior during this period that will either protect or place them at risk for years to come (9).

Prevention programs for youth are thus vital because they may protect young people now and promote the development of safer sexual behaviors that will protect them into the future.

Investigators have described the results of individual AIDS prevention programs directed at youth. Jemmott et al. described an intervention for African-American male adolescents (10). Kipke et al. recruited inner-city African-American and Latino youth for a three-part AIDS education intervention that changed knowledge, behavior, and behavioral intentions (11). New York City's main jail facility for male youth aged 16-19 years was the setting for another intervention study that changed certain risky sexual behaviors but found that substance use behaviors may be more difficult to change (12). Changes in knowledge and risk behavior associated with an HIV prevention program targeting urban adolescent males and the effect of condom promotion and distribution programs have been described (13,14). The literature contains examples of individual adolescent AIDS prevention efforts; however, little is known about the process of conducting effective interventions or examined lessons learned across programs.

In 1988, the Robert Wood Johnson Foundation (RWJF) provided approximately \$18 million to fund 54 AIDS prevention and service projects throughout the United States and Puerto Rico. These projects targeted a variety of populations, used diverse intervention activities, and were delivered by widely differing organizations. A process evaluation of the RWJF AIDS initiative was conducted to identify lessons learned across the 54 projects. This article focuses on diverse prevention projects that targeted their educational and skill-building efforts at adolescents. It is a descriptive evaluation of the HIV prevention strategies considered by staff of the initiative.

Methods

A combination of quantitative and qualitative methods were used in this process evaluation to measure intervention effectiveness (15,16). Quantitative data were collected through a mailed survey that explored issues related to prevention activities, service activities, and administrative aspects of the project. Qualitative data collected through interviews, site visits, and focus groups identified the factors perceived to have facilitated intervention effectiveness and illuminated the meaning of survey responses. This integrated methodology was used to explore more

thoroughly the meaning of program activities. A detailed description of the methodology and data analysis strategies has been reported elsewhere (17).

Quantitative Data Collection

Staff of all 54 RWJF-funded AIDS projects were contacted. The survey included closed- and open-ended items in three sections related to: (a) prevention activities directed at individuals/groups believed to be at risk for infection with HIV; (b) service activities directed at individuals/groups known to be at risk; and (c) other larger administrative issues. Information about the project was affiliated with the organization. Items drawn from the survey in the first section are reported here. Information about the project's target population, recruitment and retention strategies, and intervention activities is reported elsewhere (18).

Regarding 30 different intervention activities and their perceived effectiveness, the survey requested the following information: "Different community-based AIDS projects use different techniques to achieve their objectives. Please indicate which of the following activities is a part of your RWJF-funded project, and rate its effectiveness on a scale of 'not at all,' 'somewhat,' and 'quite useful.' The list of intervention activities included distributing educational materials, producing videotapes, conducting support groups, conducting small group (under 15 participants) or large group (15 or more participants) discussions, training peers or volunteers, providing drug use kits, and referring participants to medical care or drug treatment. After listing the specific intervention activities used by their project, respondents were asked to list the three most effective and the three least effective.

Respondents were also asked to list the three most and three least successful funding sources ("List the three most and three least successful funding sources contributing to the project's accomplishments ('What have been the major successes/accomplishments of the project?')/accomplishments of the RWJF-funded prevention project has been the most successful?"). Respondents were also asked to list the three most and three least successful funding sources ("What have been the major problems/problems that your RWJF-funded project has encountered?"), and staff were asked to list the three most and three least successful funding sources ("What have been the major problems/problems that your RWJF-funded project has encountered?").

Responses were collected in three waves during the project duration of RWJF funding so that the project's staff received the survey at different points in their funding cycle to capture the range of their project implementation experiences. The survey was mailed out with the understanding that responses were

voluntary and confidential, and that continued funding was not dependent on the survey's completion. Fifty-one surveys (94%) were returned.

Qualitative Data Collection

The second component of the data collection was to obtain qualitative data during in-depth site visits using a complex case study design. A maximum variation sampling strategy was used to select sites that varied widely in terms of population served, intervention strategies used, funding sources, type of funding, and geographic location. The goal was to choose a diverse group of sites that would highlight the myriad of prevention approaches under way across the country with different target populations.

Twelve site visits lasting 2-4 days each were conducted. Researchers completed in-depth interviews with project directors, health educators, outreach workers, evaluation specialists, community health officials, and directors of other community-based agencies. Interviews typically lasted 30-60 min; skip patterns and targeted probes allowed for flexibility and comprehensiveness. In addition, focus groups were conducted with members of the target population and participant observations were made of intervention activities whenever possible.

Data Analysis

Frequencies and descriptive statistics were computed from the questionnaire data. Effective intervention strategies were identified. The in-depth interviews yielded a rich description of the barriers and factors that contributed to the success or lack of success. Qualitative data were analyzed using a systematic process (19) to categorize, synthesize, and identify common themes across respondents. The project

Description of the Youth Sample

For the purposes of this article, projects targeting youth were defined as those whose target populations consisted of at least 60% youth, and adolescents. Eleven of the 54 RWJF-funded projects met this definition; six of these received in-depth site visits during which 71 interviews, 11 focus groups, and 10 intervention observations were conducted. Of the 11 projects whose target population consisted of at least 60% youth, 8 focused exclusively on adolescents while 3 focused on other audiences as well.

Results presented here are drawn from quantitative survey data reported by all 11 sites with supplemental information taken from the 6 sites for which consolidated case studies are available.

While all 11 projects targeted adolescents, there was considerable variation among them. The intervention setting (e.g., school or non-school based), delivery mechanism (e.g., professional health educator or peer educator), intervention activity (e.g., teacher-led or small-group discussion), whether AIDS information was integrated with other health-related information for target population (e.g., runaway and homeless youth), project duration, level of funding, and nature of the relationship with the implementing organization varied. Table 1 contains descriptive information on several key characteristics of the projects.

Table 2 contains information on the intervention activities reported by the 11 youth projects and an assessment of their effective elements as provided by survey respondents. Prevention projects directed at youth contained many similar elements. All of the projects used small- and large-group discussions, and small-group discussions were included among the most effective activities by 72.7% of projects that used them. Another common component was the involvement of peers or volunteers in prevention activities. All 11 projects reported using peers and/or volunteers to deliver educational messages to at-risk youth, and 10 included it among their most effective activities.

Despite considerable variation among projects, several themes emerged from open-ended survey questions, in-depth interviews, and observations of intervention activities central to the youth projects: benefits and challenges of peer education, importance of addressing gatekeeper needs, and use of structured settings to reach youth.

All 11 youth projects reported involving peers in their intervention activities. One project, for example, used teenagers as AIDS 101 ambassadors, or health educators, to work in runaway shelters. Another project employed teen actors to develop a series of interactive radio vignettes based on shared experiences. A third project involved peers as role models and discussion leaders in school-based settings.

The use of peer educators offered several strategic advantages to AIDS prevention projects. First, staff

Table 1. Descriptions of 11 RWJF-funded AIDS prevention projects for youth

Project Name	Location	Duration	Target Populations	Intervention Setting	Data Source(s)
Advance Human Services Teatro AIDS Prevention Project	Los Angeles County and southern CA	12 mo	Latino youth (mostly male) who are currently or formerly in the foster care system, homeless, and at risk of becoming homeless (near and far)	Community groups, social service agencies, churches, and homeless shelters available to the target population	Survey only
Boston University	Boston, MA	12 mo	Youth, including those with social and emotional problems, who are referred to professionals for evaluation and treatment	Private homes with case managers, community centers, and facilities with professional staff	Survey only
Catholic Counseling Center AIDS Prevention Program	Cleveland, OH	36 mo	Disenfranchised youth (hardcore) through 20th grade	Public and private schools, churches, and community centers	Survey and site visit
Girls, Inc. AIDS Education Project	New York City (headquarters)	24 mo	Girls between ages 12 and 18, after-school program	Schools and other settings used by local Girls, Inc. affiliates	Survey and site visit
Good Samaritan Project Teens Teaching AIDS Prevention	Kansas City, MO	12 mo	Youth, including HIV-positive youth, who are currently in the foster care system	Anywhere a telephone is available, schools, social and day care organizations	Survey only
Grant County Nurses Office	Rural Wisconsin	24 mo	Youth attending school in Grades 7-12, rural teachers, parents, and youth	Elementary and secondary schools	Survey only
Seattle-King County Department of Public Health Mod Project	Seattle-King County, WA	24 mo	Gay and lesbian youth, including those who are currently in the foster care system	Local social centers, youth centers, schools, storefronts, and locations available to the target population	Survey and site visit
Southcentral Foundation AIDS Education and Personal Choices	Anchorage, AK	24 mo	Alaska Native youth, including those who are currently in the foster care system	Elementary and high schools, summer youth centers, and other locations	Survey only
Southeastern Network AIDS Prevention for Youth in Runaway Centers	Atlanta, GA (headquarters)	24 mo	Runaway and homeless youth, including those who are currently in the foster care system	Runaway centers and other locations	Survey and site visit
University of IL-Chicago Adolescents' AIDS Education Program	Chicago, IL	24 mo	African American and Hispanic youth, including those who are currently in the foster care system	Two predominantly African American and two predominantly Hispanic public high schools	Survey and site visit
Westchester County Health Department Intimate Realities	Westchester County, NY	24 mo	Predominantly African American and Hispanic youth, including those who are currently in the foster care system	Elementary and high schools, summer youth centers, and other locations	Survey and site visit

Table 2. Descriptions of intervention activities from the survey

Project Name	Description of Intervention	Number of Activities Rated Most Effective*
Advance Human Services Teatro AIDS Prevention Project	Provide theatrical education through curriculum materials, English and Spanish theater groups, and a theater for the visually impaired.	Peer leaders; conduct small group discussions; conduct large group presentations
Boston University	Provide information on AIDS prevention and risk reduction through a series of workshops.	Produce videotapes; conduct small group discussions; provide inservice training
Catholic Counseling Center AIDS Prevention Program	Raise awareness of HIV/AIDS through a series of workshops, support groups, and community events.	Conduct support groups; conduct small group discussions; train peers or volunteers
Girls, Inc. AIDS Education Project	Train girls in the use of condoms and other methods of contraception.	Produce own written educational materials; conduct small group discussions; provide inservice training
Good Samaritan Project Teams Teaching AIDS Prevention	Provide peer-led AIDS prevention education to teens, providing support, care, and treatment.	Establish a telephone hotline; conduct small group discussions; conduct large group presentations
Grant County Nurses Office	Develop AIDS education materials and provide information on AIDS prevention.	Conduct small group discussions; distribute educational materials produced by a different organization; train peers or volunteers
Seattle-King County Department of Public Health Mod Project	Develop AIDS prevention materials and provide information on AIDS prevention.	Produce radio/TV announcements; train professionals in the community; creative activities including theater, mural, and poster projects
Southcentral Foundation AIDS Education and Personal Choices	Create a support group for African American people and provide information on AIDS prevention.	Educate elementary aged students; educate high school aged students; educate out-of-school students
Southeastern Network AIDS Prevention for Youth in Runaway Centers	Create a support group for runaway youth and provide information on AIDS prevention.	Produce videotapes; conduct small group discussions; produce own written education materials
University of Illinois Chicago Adolescents' AIDS Education Program	Offer AIDS education to high school students through a series of workshops and support groups.	Train peers or volunteers; conduct small group discussions; conduct large group presentations
Westchester County Health Department Intimate Realities	Provide AIDS education to high school students through a series of workshops and support groups.	Provide inservice training; conduct large group presentations; produce graphic arts educational materials

* From a list of 30 different intervention activities.

reported that prevention messages developed by teens were often more culturally and linguistically appropriate. Peer educators can use the contemporary vernacular of a particular subpopulation of youth, thereby making the messages both more accessible and credible. The importance of determining what resonates with youth audiences was a recurrent theme. Second, the added responsibilities and prestige associated with being a peer educator reportedly enhanced these youths' self-esteem. Staff reported that peer educators developed a sense of ownership and urgency about the nature of their work.

Staff reported that recruiting and retaining sufficient numbers of competent peers and volunteers is one of the primary challenges facing youth projects. The competing demands of school, work, and family made it difficult for many teens to take on additional activities.

The nature of the work itself is another challenge in recruiting teen peer educators. For youth involvement in an AIDS prevention program to be, at the worst, viewed with suspicion and, at best, something for which they receive much respect from their peers. Staff reported that recruiting in these circumstances may be problematic.

Finding willing participants is only one challenge to recruitment. Finding youth with requisite communication skills, respect, and a role model of their peers, and who model safer sexual and drug use behavior is an additional challenge.

In response to these challenges, several projects developed creative strategies to compensate youth for their involvement. One program, which provided participants with a \$5/h stipend, reported that only three to four group members left during the 2-year project. Another project lobbied the local school board to offer academic credit to high school students who participated as peer educators during the school year. In addition to limiting attrition, these strategies brought other benefits to the projects. Compensating peer educators allowed projects to teach valuable lessons about life skills, sense of responsibility, and create a structure that would help retain youth leaders. Staff reported that compensation helped retain youth as peer educators.

Project staff observed that older adolescents, working with parents and other influential adults in developing interventions for teens. These adults often have strong opinions and can influence the content and type of information adolescents receive, particularly in matters related to sex. Project staff recognized the importance of balancing youth involvement

with the involvement of other adults. At the same time, such involvement may be necessary for the survival of the project. Conducted AIDS education sessions for parents and other interested members of the community to increase the number of people who could talk openly and honestly about AIDS. Staff reported that such sessions were designed to ensure that education messages received by youth at home were consistent rather than in conflict, with those received in other settings. Staff also reported that the values of the community were also important in

supporting and overcoming barriers. For one project, consistency with a Catholic community's values was an important factor in the development of an intervention that addressed abstinence and incorporated age-appropriate information about condoms. The staff sought community involvement from the beginning to gain trust, something that gave them greater flexibility and room to maneuver.

Staff reported that communities, by participating in program development activities, acquired a sense of ownership in the intervention and its success. Community visits indicated that the project was successful, while the project was able to overcome significant barriers. Project staff reported that the meetings and interactions provided a forum for

adolescents to spend much of their time in structured settings, primarily schools. Other settings in which sizable numbers of youth can be found include amateur sports programs, juvenile detention centers, shelters for runaway youth, and established after-school programs. The 17 projects surveyed, 7 worked within a structured setting, 10 worked with youth in detention centers, and another worked with rural runaway youth through shelter programs. Several projects worked through sports programs and after-school programs. This overall 80% of the projects in this study targeted youth accessed through structured settings. Staff reported that the relative ease of access to the target population is the most obvious benefit of working with institutions that serve youth.

School-based programs have the added advantage of being able to create groups to facilitate intervention. The project assigned health educators to develop appropriate interventions for different grades. Even staff working in school-based after-school programs noted the importance of the strength

of school-based settings was perhaps clearer for project staff without access to structured settings. Project staff working with runaway youth remarked on how hard it was to develop appropriate messages for youth of different ages, particularly if the setting does not allow for easy segregation.

A number of projects confronted these challenges by sending project staff into the schools to work directly with teens. Staff observed that this technique enabled them to take advantage of schools' accessibility, while the presence of a trained health educator, one without a formal connection to the school, helped create a more comfortable environment. Other projects approached this challenge by asking adolescents to identify the teachers in their schools whom they would like to have trained to be AIDS educators. Respondents noted the importance of working with adults within structured settings.

One of the most obvious limitations of working with structured settings is the fact that many youth at highest risk have no or minimal contact with these institutions. Project staff working with runaway youth noted, in particular, the frequent contact with youth leave and change schools. As a result, many of these teens do not participate in an ongoing AIDS prevention program offered as part of a school health education curriculum. Similarly, project staff noted that there is little opportunity to repeat or reinforce messages over time with transient youth populations such as runaways or those in juvenile detention facilities.

Discussion

All of the RWJF-funded AIDS prevention projects directed at youth contained elements deemed effective by project staff. While the use of peers and volunteers, endorsement of adults, and availability of structured settings may improve the delivery of safer sex and drug use messages intended for any audience, these components were assigned to a particular importance in delivering credible, targeted messages to young people. Yet all three elements position AIDS prevention projects in the complex terrain between success and failure, and the decision to use these strategies may not always be easy to make.

Peer influences in AIDS prevention and education, both positive and negative, have been well documented in the literature (29,30). Peer education programs directed at young people are one attempt to promote safe behavior and growth norms in support of these activities. The use of contemporary

vernacular, relevant local examples, and modeling of credible, respected peers can greatly assist AIDS prevention efforts. One concern about these efforts is the extent to which the peer educators are able to influence the health outcomes of their peers at a level beyond knowledge and attitudes. Compared to the target audiences, peer educators receive the most intensive training and repeated safer sex messages, and are typically likely to have greater knowledge, changed attitudes, and acquired and practiced relevant skills. A related issue is the extent to which project administrators have quality control over the delivery and content of AIDS prevention messages. This is a potential concern whenever train-the-trainer approaches are used, but is perhaps particularly relevant when involving young people. Supervision of these instances may be labor intensive both to ensure quality programming and to aid retention.

Support from parents, extended family, teachers, clergy, and other influential adults may be necessary when trying to reach young people, particularly when most are under adult supervision. The advantages of adult involvement, however, may not outweigh the disadvantages. Researchers suggest that parental involvement does influence adolescent sexual activity, may reduce the risk of HIV transmission, and can affect the content and delivery of HIV prevention messages (27,30). On the other hand, youth may be distrustful of programs that have the imprimatur of parents and other adults. They may fear that such programs will not adequately safeguard confidentiality. Each adolescent AIDS prevention project must balance the importance of using influential adults to reach youth in the target population and the potential harm to recruitment and retention that may result from reduced credibility.

AIDS educators need to establish programs wherever young people congregate (31). While AIDS prevention efforts directed at youth have used a variety of established locations (24,32-34), little discussion has been paid to the role of structured settings. Because most youth spend considerable time in some sort of structured setting or activity, these places are logical points of access. Schools, after-school programs, amateur sports programs, detention centers, and runaway shelters all provide reasonable, consistent access to youth in need of AIDS prevention information. Nevertheless, certain settings, notably schools, may be least effective in terms of attracting and reaching those young people at greatest risk of acquiring HIV. Youth who are disaffected or emotionally disengaged from

school, have dropped out, or only infrequently attend class have scant opportunity to take advantage of school-based AIDS prevention programs. Surveys of out-of-school youth reveal that they are at significantly higher risk for HIV than their in-school peers (2,20). Health educators seeking to prevent the spread of HIV into these communities of youth will need to identify other settings or delivery mechanisms to reach this population.

Study Limitations

One limitation of this study is that only the 11 chosen projects received in-depth site visits. While not randomly selected, these sites represent a wide variety of programs. We found that the experience of providing AIDS interventions to youth was more similar than dissimilar regardless of whether survey or in-depth case study data were available. Nevertheless, a larger random sampling of programs could provide greater generalizability.

A second limitation is that data were collected from a process, rather than an outcome, evaluation. Thus, the findings represent impressions of intervention effectiveness gleaned from project staff and based on their experiences in the field. The actual effectiveness of these intervention strategies was not examined. In the absence of such outcome data, however, this study can still be used to inform planning and project implementation for AIDS prevention among youth.

Conclusions

Several intervention activities were judged most effective by staff working at 11 AIDS prevention projects targeting youth. These included small and large-group discussions, videotaping, role playing, and peer support groups, and providing opportunities for adolescents to meet and work with people with AIDS. In addition, three elements were particularly important when delivering prevention messages to youth: the role of peer educators, endorsement of adults, and access to youth through structured settings. Health educators, teachers, and other persons working with young people would do well to consider these factors when developing, implementing, and evaluating AIDS prevention programs for youth.

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April 30, 1997

Ms. Sandy Thurman
Director
Office of National Aids Policy
808 17th Street, N.W.
8th Floor
Washington, D.C. 20006

Dear Sandy:

Congratulations on your new position as Aid's Czar for the President. I wish you success in your new role.

I send heartfelt congratulations and best wishes in your new endeavor.

With warm regards.

Sincerely,



Reta J. Lewis

RJL/de
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*Go Girl!!
Let's go to lunch!!*

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Protease Inhibitors

Rethink Your Options, Understand Your Choices

by Billy Pick

With the advent of new drug therapies, specifically the protease inhibitors (PIs), many people living with HIV have a newfound sense of hope. The task of making informed choices about how to most appropriately utilize the available therapies has become the focus of much discussion. Research surrounding HIV is constantly changing and being updated. There is no clear cut scientific or medical consensus. Access to treatments which appear to be at least partially effective against the HIV virus has led people with HIV to raise a variety of questions regarding these drugs. We will try to address several of the more important concerns faced by people with HIV in the face of new and sometimes conflicting data.

WHEN TO START

Probably the most important question that faces those who are new to the world of anti-retroviral drugs is when to start treatment and figuring out what your treatment goals should be. In the past, there had been a tendency to wait until a person's CD4 count had fallen to at least below 500 to initiate antiretroviral treatment. This was due in part to the theory of latent HIV infection. It was felt that after the period of acute infection that there was a prolonged period where the virus was not very active. The idea was that if a person was asymptomatic and it appeared that their immune system still seemed to be functioning then that person should wait to initiate therapy until they presented with certain clinical manifestations. Physicians did not want to "use up" the limited repertoire of antivirals until there appeared to be an immunologic

decline. Today, we know that HIV is constantly replicating from the moment of infection and therefore has a profound impact on the immune system early on.

At present, the consensus among knowledgeable providers is to hit the virus hard and to hit it early. The question is how early is early. A group of prominent international AIDS specialists published a set of treatment guidelines for HIV/AIDS in the *Journal of the American Medical Association* in July, 1996. They recommended antiviral treatment be started for HIV positive persons when they:

- 1) Exhibit symptoms of HIV, such as unexplained fevers, night sweats, weight loss and HIV-related conditions not defined as AIDS but due to immune compromise, such as Candida infections or oral hairy leukoplakia;
- 2) Have a high viral load, whether or not the CD4 count is over 500, and even if there are no symptoms. A high viral load was defined as being more than 30,000 – 50,000 copies, although they also stated that therapy be considered for viral loads greater than 5,000 – 10,000 copies.

The committee guidelines allowed for deferring treatment if the CD4 count is stable between 350 – 500, viral load levels are below 5,000 – 10,000, and there are no symptoms related to HIV. These guidelines are already dated and the subject of much debate. Most knowledgeable practitioners feel that it is important to treat anyone with a detectable viral load in order to inhibit viral replication as much as possible. Even though one study (Mellors) found that only 8% of men who had

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