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LONG ISLAND UNIVERSITY

ARNOLD & MARIE SCHWARTZ COLLEGE OF PHARMACY AND HEALTH SCIENCES
75 DEKALB AVENUE AT
UNIVERSITY PLAZA, BROOKLYN, NEW YORK 11201
Office of the Dean (718) 488-1004
Fax (718) 488-0628

September 16, 1993

The Honorable Tom Harkin
Chairman, Subcommittee on Labor,
Health and Human Services, Education
and Related Agencies Committee on Appropriations
186 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator,

I am writing to encourage your support, in the FY 94 budget, of the activities of the Foundation of Pharmacists & Corporate America for AIDS Education (FPCA).

FPCA has devised an effective plan to engage the nation's 112,000 community pharmacist, in 60,000 pharmacies in a national program of AIDS education. In a pilot program, FPCA collaborated with the U.S. Centers for Disease Control and Prevention (CDC) to develop educational materials that can be distributed through a nationwide network of community pharmacies to millions of Americans. Pharmacists are the health professionals most accessible to the public. Utilizing their expertise, accessibility, and willingness to participate in this venture is a cost-effective way to capitalize on an existing infrastructure to bring critical information into our neighborhoods.

Moreover, the model being established by FPCA represents an extraordinary coalition of business, government and academia in a program that addresses of one of the nation's most serious health problems.

Our College has a particular interest in this program. New York accounts for about 20 percent of the AIDS cases in the United States, and we are located in the downtown Brooklyn area where there is a disproportionately high incidence of AIDS. This past year, with the assistance and encouragement of FPCA, we introduced a new course on AIDS into our curriculum which provides students with information on both prevention and treatment of AIDS. It also has an experiential component which provides educational services to the community.

We look forward to an expansion of the project as proposed by FPCA, and we intend to work closely with them in the future.

I urge your support.

Sincerely,

Stephen M. Gross
Dean

Nigel L. Gragg

File chron.

THE WHITE HOUSE

WASHINGTON

November 2, 1993

MEMORANDUM TO CAROL RASCO

FROM: KRISTINE GEBBIE

My apologies for a very tardy response to your query on the Interagency Council on the Homeless.

I'm delighted that a mechanism to continue the Council has been found. Issues of homelessness and HIV infection are complex, and this Council has filled an important role. If appropriate under the new structure, I'd like to have staff representation at meetings of the Council to foster clear communication in HIV-related issues.

NOV - 1 1993

THE WHITE HOUSE

WASHINGTON

FAX COVER SHEET

OFFICE OF THE ASSISTANT TO THE PRESIDENT FOR DOMESTIC POLICY
SECOND FLOOR, WEST WING
THE WHITE HOUSE
WASHINGTON, DC 20500
(202)456-2216 PHONE
(202)456-2878 FAX

TO: Kristine Gebbie

FAX #: 632-1096

FROM: CAROL H. RASCO

DATE: 10/21/93

NUMBER OF PAGES (including cover sheet): 2

COMMENTS:

If you have any problems with the fax transmission, please call _____ at (202)456-2216.

THE WHITE HOUSE

WASHINGTON

October 21, 1993

MEMORANDUM FOR MEMBERS OF THE INTERAGENCY COUNCIL ON THE HOMELESS

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

SUBJECT: Continuing the Work of the Interagency Council

As you know, the Congress chose not to fund the staff and operations of the Interagency Council on the Homeless (ICH) in FY 1994. The Council was created by the McKinney Act in 1987 to coordinate Federal policies and provide leadership for activities to assist homeless individuals and families.

Ordinarily, I would bring the issue of how to continue the work of the Council to the DPC for discussion. However, because there is to be a Congressional hearing on this next week, and given the importance of providing for continuous policy coordination on homeless issues, I would like to propose to you a way of proceeding and get your reactions as soon as possible.

It is important that we signal to the public, the Congress, and all of the agencies with programs and policy interests involving homelessness that, despite the unfortunate loss of funding for ICH, its valuable work will be carried on.

To that end, I suggest that the Council's role as a neutral policy forum be continued by asking its current members to serve as a new working group of the DPC. Its executive director, Marsha Martin, could function in an adjunct capacity as liaison to the DPC. Secretary Cisneros has indicated that HUD will shoulder the cost of continuing the operations and administrative coordination functions of the Council.

It seems to me that this arrangement offers strengthened White House involvement on issues related to homelessness as well as a neutral forum for the discussion and resolution of interagency issues.

Please share any feedback with me as soon as possible and certainly no later than NOON MONDAY, OCTOBER 25.

Thank you.

cc: Domestic Policy Council members outside the ICH

file

THE WHITE HOUSE

WASHINGTON

November 3, 1993

MEMORANDUM

TO: Jarrett Clinton, Administrator
Agency for Health Care Policy and Research

FROM: Kristine M. Gebbie W. Steve Lee for
National AIDS Policy Coordinator

SUBJECT: HIV Management Guidelines

Thanks for sharing the HIV management guidelines -- you, your staff and the panel have done an outstanding job. I have sent the attached note to Phil Lee.

There are a few areas where a slight change might be helpful. I'll list these out for you. None is big enough to hold up production or release if you think there would difficulties with them. These are:

Executive Summary
Page 2: In the summary version, the reference to "provider disclosure on HIV status to patient" almost sounds like disclosure of the provider's status to the patient. Please consider re-wording.

Forward
Page iii: The phrase "in the overwhelming presence of HIV in every community" overstates the presence of the infection for much of the U.S.

Body of report
Page 29: Provider Disclosure to Agencies. I think it would be worthwhile to mention that both TB and Syphilis, discussed extensively in the document, are reportable in all jurisdictions and will trigger disclosure of limited information to a health department.

Page 75: In discussing adherence to a TB regimens it may be worthwhile to note that many local health departments provide public health nursing staff to work with complicated or reluctant patients. The provider doesn't have to struggle alone.

THE WHITE HOUSE

WASHINGTON

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MEMORANDUM

TO: Dr. Phillip Lee
Assistant Secretary for Health

FROM: Kristine M. Gebbie W. Steinhoe for
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SUBJECT: HIV Management Guidelines

The AHCPR has shared with me the recently completed Guidelines for Evaluation and Management of Early HIV Infection. I have reviewed the materials. While I provided a couple of possible edits to Dr. Clinton, the document as it now stands is appropriate for release. I hope publication and release to practitioners can happen quickly. It is clear and to the point on an area of HIV care in which more and more practitioners across the country are involved.

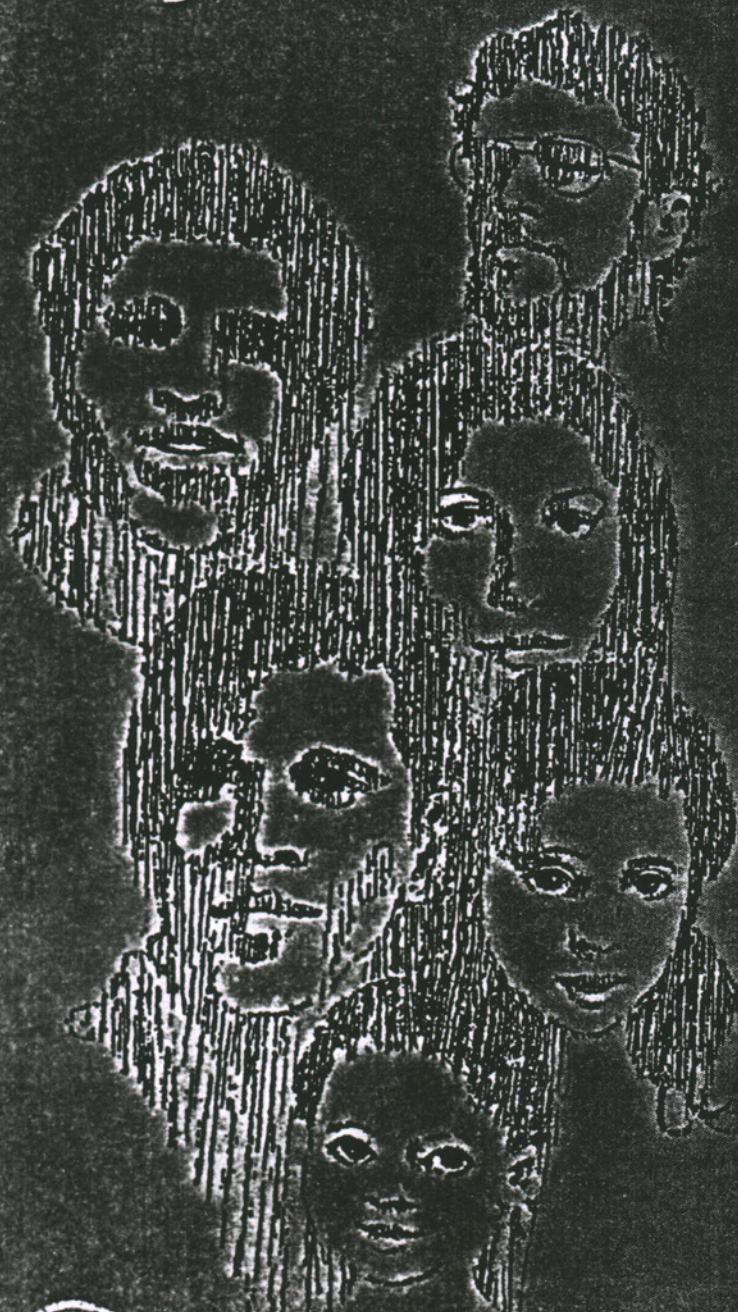
Please let me know if I can help this process along.

cc: Dr. Jarrett Clinton

Cover - Practice Guideline

DRAFT

Evaluation and Management of Early HIV Infection



U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research

Clinical Practice Guideline

text to Bob Jackson 1/3/94. Steve

THE WHITE HOUSE

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fwb

THE WHITE HOUSE

WASHINGTON

November 3, 1993

MEMORANDUM FOR CAROL RASCO

FROM: Kristine M. Gebbie

SUBJECT: Weekly Report Beginning November 3, 1993

THE WEEK AHEAD

Presentations

Reading/Philadelphia

"Dealing with the AIDS Crisis: New Directions" Symposium at the Franklin Institute. Federal AIDS Policy.

Baltimore

National Pediatric/Family HIV/AIDS Project Meeting and local community groups. HIV/AIDS and the Health Care Reform Proposal.

Johns Hopkins University, Milton S. Eisenhower Symposium "AIDS Policy." Federal AIDS Policy.

Meetings

Philadelphia

Group discussions and site visits with local community leaders, including ACT UP, on AIDS prevention, care and research.

Washington

AIDS Education in the Federal Workplace briefing with senior White House staff.

HRSA staff briefing on Titles I and II of the Ryan White Community Care Act, health care reform, and other HRSA programs.

National Institute of Nursing Research, Association of State and Territorial Health Officials, Project Inform, and National Leadership Coalition on AIDS.

Baltimore

AIDS Task Force of Delaware-Maryland Synod of the Evangelical Lutheran Church. Federal AIDS policy.

THE WEEK IN REVIEW

Presentations

Chicago

"Women in Government" conference. Women and AIDS, and women in government service.

Washington

American Association for the History of Medicine, National Board of the Medical College of Pennsylvania speeches.

Chief Nurse of the Public Health Service to discuss nursing's role in AIDS and federal AIDS programs.

Boston

Harvard University Kennedy School of Government and Harvard AIDS Institute. AIDS policy issues and health care reform.

Massachusetts Public Health Nursing Centennial Celebration, "Looking Back and Looking Ahead: 100 Years of Public Health Nursing in Massachusetts." AIDS and public health nursing.

New Orleans

National Skills Building Conference. Community-level roles in AIDS education, prevention, and care, and CDC guidance on community planning.

Reading/Philadelphia

University of Pennsylvania School of Nursing, and Reading Hospital. Nursing, and AIDS in the U.S.

Merck Industries Vaccine Division. Site visit and seminar for Merck staff on prevention research and care.

PRESS

New York Times and National Public Radio on GP160.
Local press in New Orleans, Boston, Reading in conjunction with appearances.

THE WHITE HOUSE

WASHINGTON

File Copy

copy to George for Health reform files

November 3, 1993

MEMORANDUM

TO: Clif Gaus

FROM: Kristine M. Gebbie /s/
National AIDS Policy Coordinator

SUBJECT: DHHS information systems

I have reviewed the draft The U.S. Health Care Information System: Design and Use Under Health Care Reform. Sorry, I'm slow in getting you comments, but I would suggest adding the following:

> Page 2: Existing state and national protection for records associated with conditions such as HIV infection, AIDS and substance abuse treatment may need to be revised under the new system. Any revisions must take into account the need for protection from disclosure and prevention of discrimination against vulnerable individuals.

Thanks -- this is a great step in explaining the planned system.

COPY FOR YOUR INFORMATION

Sent 10/27/93 cn

Note to: Dr. Phil Lee
Dr. Jo Boufford
Dr. Joycelyn Elders
Dr. Roz Lasker
Bill Corr
Christine Gebbie

From: Clif Gaus

Date: October 6, 1993

The enclosed paper was developed by HCFA & PHS staff in response to a request from OMB and is an effort to develop a "broad vision" for DHHS of information systems under health reform.

Your comments would be especially useful by 10/13. Sorry I'm slow

Clif – I would suggest addition on

P2 of

Existing state & national protections for records associated with conditions such as HIV infection, AIDS, and substance abuse treatment may need to be revised under the new system. Any revisions must take into account the need for protection from disclosure & the prevention of discrimination against vulnerable individuals.

Thanks – this is a great step in explaining the planned system

Kristine

Draft for Comment
Do Not Reproduce
or Distribute

The U.S. Health Care Information System:

Design and Use under Health Care Reform

Prepared by:

The DHHS Health Reform Implementation Task Force

October 1, 1993

Table of Contents

Executive Summary

Purpose. The American Health Security Act, the President's plan for health care reform, includes provisions for uniform administrative health data and a data network for sharing data for specific purposes. Many decisions must be made about the information system for the U.S. health care system. A key decision is:

How the system will be configured --

- As an integrated information network, centrally managed, collecting complete information on health care services, and providing data and services to health system organizations?

or

- As autonomous local data systems, handling data independently, reporting selectively to a national database, and disseminating information under local policies and methods?

This paper shows the benefits of an integrated information network by describing:

(1) a framework for an integrated information system that takes advantage of major recent advances in information technology,

(2) the efficiencies of such a system,

(3) how such a system can serve the data needs of health system organizations, and

(4) the broad scope of other uses of such a system.

Design of the Information System. An integrated health care information system will function as a data storage, processing, retrieval, and analysis system for the organizations operating and overseeing the reformed U.S. health care system. Providers, health plans, health alliances, and State agencies will submit data to an information network -- using uniform forms, standard coding, and electronic transmission. Each of these health system organizations will have on-line, real-time access to their own data as well as access to data supplied by other organizations when authorized. Access to other sources of data will be subject to specific limitations that, first and foremost, will protect the privacy of individuals. All access to data will be governed by the Data Protection and Security Panel of the National Health Board.

Technology exists today to build such an information system and to provide immediate access to data. The information system will be an integrated data system with components (e.g., enrollment and encounter components) that can be connected through common linkages and protected by limited-access security systems. Data will be stored on large mainframe computers. The mainframes will act as servers of data to wide-area and local-area networks of personal computers. Personal computers will be used to access the mainframe and analyze data through specially designed system software. This software will provide immediate access to the original data, analytic tools for combining and examining those data to user specifications, and aggregate statistics important for health system management.

Initially, such a system will contain administrative records required for the operation of the health care delivery system. Eventually, the information system will add other capabilities. Such capabilities could include electronic funds transfers, telecommunication services, point-of-service data entry, early warning systems for epidemiological investigations, and eventually, detailed data for clinical decision-making.

Increased Efficiency of an Integrated System. A fully integrated information system will be more efficient than autonomous data systems throughout the health care industry because:

- the major costs of building an integrated system -- staffing for design, development, and system validation -- can be incurred once rather than multiple times by plans, alliances, States, and regional data centers;
- the computer hardware costs of such a system -- storage and processing capacity -- have declined so dramatically in recent years that they no longer represent an obstacle to a complete, integrated information network;
- the cost and burden on health plans, alliances, and States of responding to numerous requests for data will be transferred to the data centers where it can be handled efficiently with many fewer staff overall;
- a central authority will establish procedures to protect the privacy of individual records which is now done with varying effectiveness under separate State statutes;
- the resources, capacity, and access to information across States and localities will be equalized; and
- the cost to data users of gathering information from many different sources will be reduced so dramatically that it will cause a surge in research and new discoveries for improving the health care delivery.

Serving Health System Organizations. The system will be configured with a few regional data centers, as required by the Administration's health care reform proposal. The regional data centers will provide immediate access for data transactions to the data sources. Another data center will coordinate the regional centers into an integrated system and will be a single source for developing special files or software for authorized research. It also will be a central repository of data and a backup system for the regional data centers.

The Federal government will fund the infrastructure for the system and will specify standards for data collection, transmission, security, retrieval, and reporting. The system will include flexibility to support local specifications of data elements and reports. The system will provide data and analytic support to plans, alliances, and States so that they can be relieved of the expense and effort of supporting large data systems. As a result, plans, alliances, and States will be able to spend their resources analyzing data and managing the health care delivery system.

Uses of the System. An integrated information system will improve the capacity for and efficiency of health system management, including monitoring spending and developing budgets, establishing premiums and adjusting for risk, negotiating rates with providers, coordinating benefits of multiple insurers, monitoring performance and quality, providing consumer value information, and detecting fraud and abuse.

Such a system also will serve the needs of research, including public health and epidemiologic surveillance, program evaluation, survey research, and medical effectiveness and outcomes research. The need for many special-purpose and expensive data collection systems will be reduced or eliminated by a complete integrated health care information system.

Conclusion. A less than universal approach to data collection would represent a false economy and would undoubtedly result in higher costs to providers, plans, alliances, and States and other users of health care information. Placing the burden of responding to requests from numerous organizations on the many suppliers of data to the system would raise the administrative costs associated with health care delivery and data management under health care reform.

Preface

This is a planning document which is intended to stimulate discussions about a U.S. health care information system under health care reform.

The document was prompted by discussions of the Work Group on Database Building of the DHHS Health Reform Implementation Task Force. The Work Group includes representatives[1] from the:

- Agency for Health Care Policy and Research (AHCPR)
- Health Care Financing Administration (HCFA)
- National Center for Health Statistics (NCHS)
- Office of the Assistant Secretary for Management and Budget (OASMB)
- Office of the Assistant Secretary for Planning and Evaluation (OASPE)

In addition, the paper was guided by staff of the Office of the Assistant Secretary for Health.[2] The paper also has been influenced by discussions between staff of the Public Health Service and the Office of Management and Budget regarding the need for and uses of a nation-wide health care information system.

The paper is a draft for reactions by these and other groups. It is intended as a dynamic document that will change as the design of the new health care system is established through the legislative process.

---

[1]Work Group members: Joe Broseker (Chair), HCFA; Rosanna Coffey, AHCPR; Ed Hunter and Bob Pokras, NCHS; Walter Davis, OASMB; Larry Lacy and Linda Blumberg, OASPE; correct names and add HCFA staff.

[2]OASH staff: Cliff Gaus, Senior Advisor to the Assistant Secretary for Health and Jim Scanlon, Director, Division of Data Policy, Office of Health Planning and Evaluation.

The U.S. Health Care Information System:

Design and Use Under Health Care Reform

The American Health Security Act, the President's plan for health care reform, includes provisions for uniform administrative health data and a data network for sharing data for specific purposes. Many decisions must be made about the information system for the U.S. health care system. A key decision is:

How the system will be configured --

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- As autonomous local data systems, handling data independently, reporting selectively to a national database, and disseminating information under local policies and methods?

This paper shows the benefits of an integrated information network by describing:

(1) a framework for an integrated information system that takes advantage of major recent advances in information technology,

(2) the efficiencies of such a system,

(3) how such a system can serve the data needs of health system organizations, and

(4) the broad scope of other uses of such a system.

I. The Vision of a U.S. Health Care Information System

The U.S. health care information system will be an integrated information system. Standard records will be created when individuals enroll in a health plan or encounter the health delivery system and when organizations are certified to provide health-related services. These records will be routinely collected by health plans, alliances, or States (and territories), which will transmit them to regional data centers. The data centers will incorporate the records into the national health information system and will provide immediate access to these records to health care delivery organizations -- health plans, health alliances, the States, and the National Health Board -- all of whom require some or all of these data to carry out their responsibilities.

Exhibits 1, 2 and 3 show, respectively, the integrated system design, how each organization will supply data to the information system, and how these organizations will use the information system to support their functions. Other organizations with an authorized need for data will access them through the health information network. To support all of the needs for health data, the information system must contain 100 percent of enrollment, encounter, and entity (provider, plan, alliance, State) data generated by the health care system.

A. Privacy

Strong privacy and confidentiality protections must be built into the information system. A nation-wide information system provides an environment for establishing consistent data security across all data sources and for limiting access to health data for appropriate uses. Existing State data systems are inconsistent in protecting patient privacy and providing access to data.

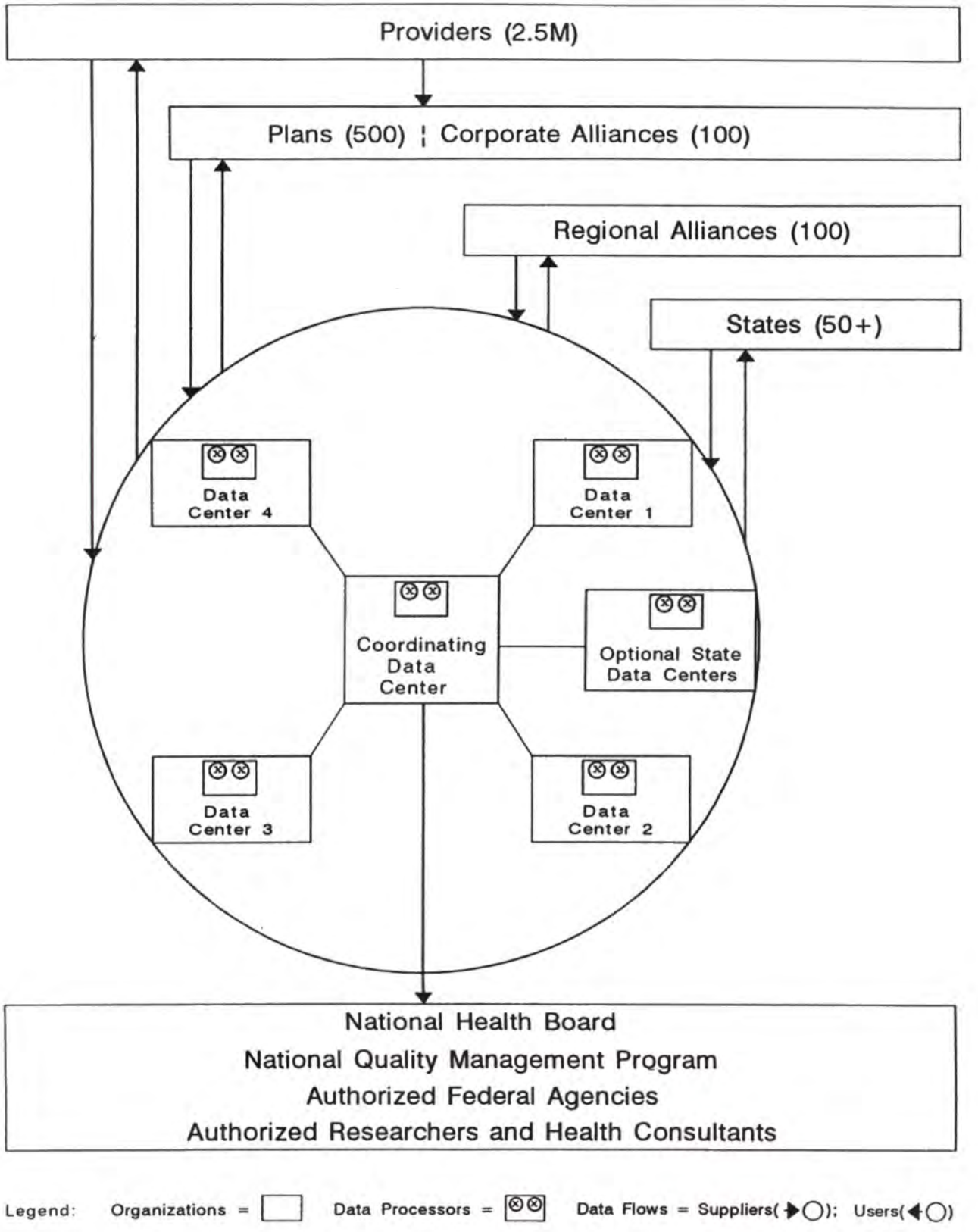
The Federal Privacy Act of 1974 and new health care reform legislation related to the privacy of health records will be the basis of legal requirements for privacy protections. New legislation is planned to:

- forbid linkages of personal health records to data outside the health care system,
- require informed consent of the individual for the various uses of health data,
- give individuals access to their own health records, and
- set penalties for breaches of confidentiality and inappropriate use of health data.

The new legislation must balance the protection of individual privacy with the need for administrative data and its value for research.

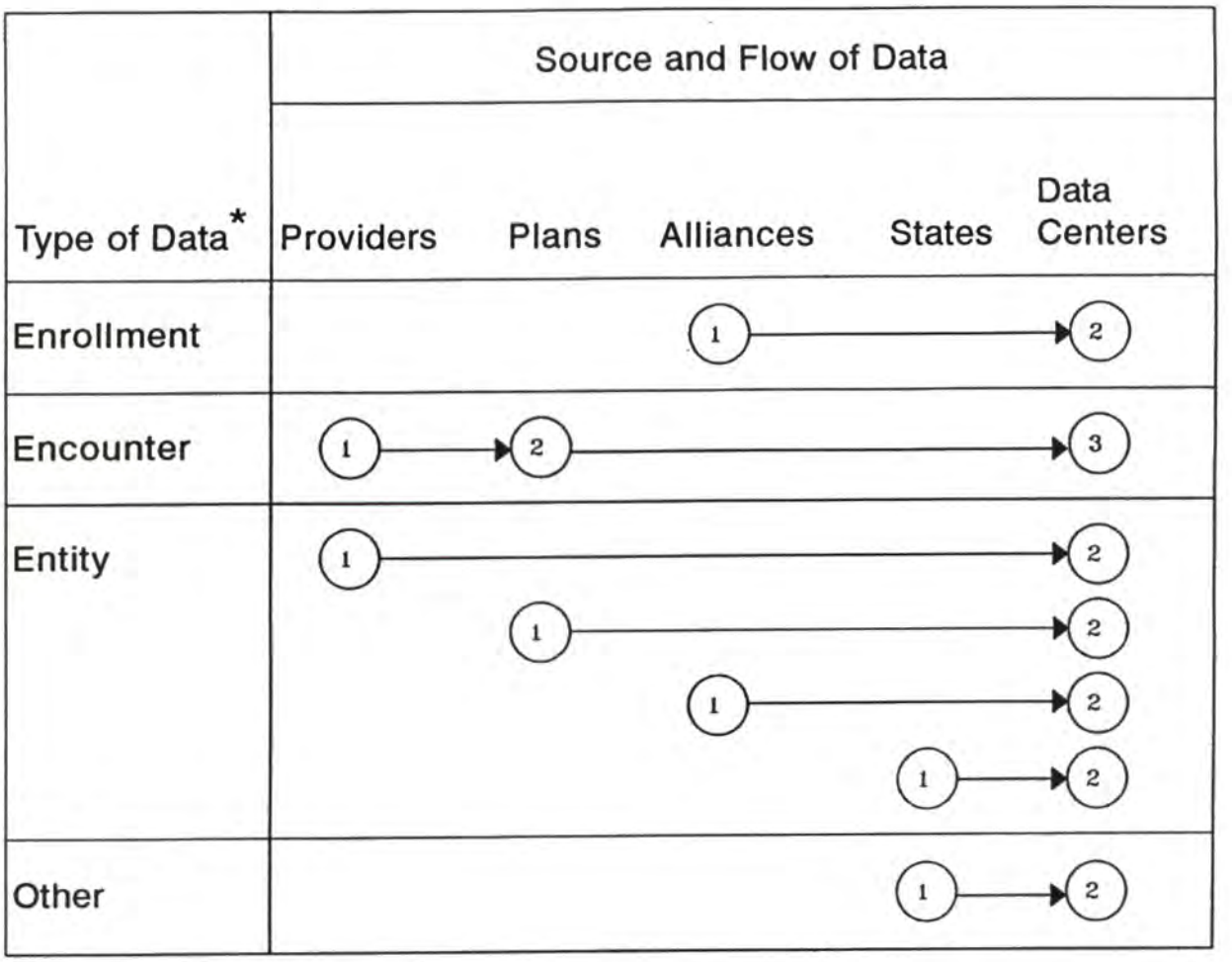
The health care reform plan includes a Data Protection and Security Panel to be appointed by the National Health Board. The panel will set policies for protecting personal privacy and will determine who will have access to which data elements at what level of confidentiality. The information system, described below, will allow components of the database to be kept physically separate so that access to specific components can be restricted.

Exhibit 1. The Flow of U. S. Health Data into Data Centers



Legend: Organizations = ☐ Data Processors = ⊗⊗ Data Flows = Suppliers(→○); Users(←○)

Exhibit 2. The Flow of U.S. Health Data into Data Centers by Type of Data



*Type of data:

Enrollment = person (and family) characteristics, employment, premium and coinsurance structure, benefits (basic and supplemental).

Encounter = encounter records, fee-for-service claims, updates of patients' health problem lists.

Entity = characteristics of the organization (provider, plan, alliance, State), licensing/certification, financial reports.

Other = Other State reporting requirements, such as Medicaid matching funds and small business/low-wage subsidies.

Flow of data:

(1) = source of data.

(1)→(2) = direct transmission to data center.

(1)→(2)→(3) = indirect transmission to data center.

Exhibit 3. Users of the U.S. Health Information System by Type of Data

Type of Data*	Users† of Data Centers				
	Providers	Plans	Alliances	States	National Users
Enrollment	✓	✓	✓	✓	✓
Encounter	✓	✓	✓	✓	✓
Entity:					
Provider	✓	✓	✓		✓
Plan	✓	✓	✓		✓
Alliance			✓	✓	✓
State				✓	✓
Other					✓

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†Users have access to all data they provide, to aggregated data of other sources, and to disaggregated data of other sources when those disaggregated data have privacy safeguards and when access to those data is authorized.

To maximize the value of the information system, it should retain identifiers of individuals (with maximum security) but severely restrict access to personal identifier for appropriate, approved uses. Appropriate uses might include:

- adjudication of claims,
- warning individuals about new discoveries of adverse effects of treatments (such as implants) they have had,
- coordination of benefits across multiple health plans for individuals,
- follow-back surveys of consumer satisfaction with health services, and
- surveys of patients receiving specific medical treatments for evaluating the outcomes of those treatments.

To obtain access to identifiers investigators will have to justify the need for identifiers, specify well-defined research protocols, and describe adequate safeguards of data on individuals. These and other issues on data security are being addressed by the DHHS Work Group on Data Access, Use, and Privacy.

B. The Integrated Information System

The information system will be an integrated data system with related components (e.g., enrollment and encounter components) that can be connected through common linkages and protected by limited-access security systems. Data will be submitted to data centers and stored on mainframe computers with large processing and storage capacity. The mainframes will act as servers of data to wide-area and local-area networks of personal computers. Personal computers will be used to access the mainframe and analyze data through intelligent system software. Standards for data collection and transmission will be established to minimize the cost of integrating data from many sources. Data will be submitted by providers, plans, alliances, and States, all of whom will use the information system to support their functions.

1. The Data Centers

The system will be run by regional data centers, as required by the President's health care reform proposal. Four or more regional centers will be directed by one "coordinating data center." Some States may elect (as permitted by the health care reform plan) to become a data center for their jurisdiction. The coordinating data center will specify the hardware configurations for all regional centers and contract to build the integrated system software. The regional data centers will provide data and services to the data sources, including immediate access to their own transactions records (i.e., enrollment, encounter, and claims and payment records). The coordinating data center will be a conduit to information for authorized

researchers and other organizations (outside the health care management system) that do not require real-time access to raw data but require access for analytic purposes. The coordinating center also will be a central repository of data as a backup system to the regional data centers.

The Federal government will fund the infrastructure of hardware, software, and staffing for the coordinating and regional data centers. The Federal government, through the National Health Board, will specify standards for data collection, transmission, security, retrieval, and reporting.

2. Hardware

In the past, it has been unrealistic to consider one integrated information system to handle the massive volume of transactions generated by the health delivery system. Fortunately, advances in computer technology now make possible what was once inconceivable. The redesign of the mainframe to emulate the parallel processing design of the personal computer means that machines for large commercial applications are much smaller and less costly than the central processing design of prior generations of mainframe computers. Furthermore, the parallel power mainframe can be tailored to the application, can be upgraded efficiently, and requires less space and accommodation (such as special air conditioning). At the same time, data compression technology makes storage of massive amounts of data feasible and relatively inexpensive.

Personal computers or workstations will be used to access data on the mainframe. Therefore, the alliances and States can use inexpensive mini- and micro-computers to access and analyze data on regional information systems or to download data (with restrictions on confidential data) to their own computing environments for analyses, if they have adequate capacity and security.

3. Software

Software systems will control various functions of the information system. Operating system software will manage the hardware. Security system software will encrypt health data during electronic transmission, decrypt data upon receipt, mask confidential data elements in databases, define levels of confidentiality, and limit access to authorized users only on a need-to-know basis. Transactions software will allow suppliers of data to add records to the database and correct existing records. Database building software will organize incoming records and construct specific files, statistics, and standard reports that meet the needs of health care managers and the research community. Database management software will control access to database components, allow linkages among components of the database for approved uses, provide on-line documentation of data elements in each database, allow authorized users to select subsets of data or combine separate databases to their own specification, and simplify analysis of the selected records. The database building and management systems are intelligent software systems that

know the structures of database components and allow the components to be combined in various ways.

Smart computer systems with wide-area networks are being used today in many industries, including banking and airline reservations. Smart software is being developed and applied to health care data assembled from different claims databases. Multiple databases are made compatible by using open analytic architecture which can be designed to combine different databases without time-consuming, up-front processing to reconfigure files for special uses. These systems are built to know the structure and coding of different databases and to know how to transform and combine them for use. Once designed, these systems combine data layouts, on-line documentation, and simple analytic tools to accelerate the availability and access to large databases that in the past have taken years to assemble into compatible structures for particular uses.

Smart software systems become intelligent with age. They will not solve all problems in health data immediately. Oftentimes inconsistencies in databases and across data sources are discovered only after careful checking or attempts to use the data for new purposes. The process of developing intelligent software for the health care information system will require an iterative process of use of the information, feedback on data quality, and modification of the software.

4. Standards

To minimize the cost of building an integrated health information system and special analytic files, the data in the system should be uniform, consistent, and interchangeable. To accomplish this, the system will require:

- system-wide data elements, including standard definitions and coding;
- unique identifiers for alliances, plans, providers, and persons;
- electronic data interchange standards; and
- standard accounting periods (e.g., one fiscal year and time-marked data entries).

In addition to standard data elements, the system will be designed with the flexibility of including optional local data elements, with registered definitions and codes. In this way, organizations will be able to tailor components of the database to fit their own needs.

4. Database Components

The information system could be designed for many purposes and types of data. In the early phase of development, essential administrative functions must be served. These include data for implementing, operating, and monitoring the

new health care system. Initially, components of the data system will include:

- enrollment records (of all covered individuals);
- encounter records (encounters or claims and payments for all covered services[3]);
- entity records (characteristics and financial data on providers, plans, alliances, and States); and
- aggregate records (statistics, available as often as weekly, generated from the information system, including enrollment, utilization, spending, quality of care indicators, and budgets of entities served by the health care information system).

Ultimately, the health information system will contain more than administrative data. For example, it should support electronic funds transfers, telecommunication services, point-of-service data entry, and eventually, detailed data for clinical decision-making.

5. The Flow of Data into the Information System

The flow of enrollment, encounter, and entity data into the health information system is shown in Exhibit 2. Enrollment records will be provided by the alliances to the data centers. Encounter records will be created by the providers, sent to the plans (in fee-for-service plans), and sent by the plans to the data centers. Entity records will be provided by each reporting organization (provider, plan, alliance, and State) directly to the data centers. In addition, there will be other reporting requirements of States such as for matching funds and subsidies. These reports will be made in standard formats through the network to the agencies responsible for Federal oversight. Each organization of the health care system will have access to its own data and access to other components of the information system on a need-to-know basis.

6. Access to Data in the Information System

Future access to enrollment, encounter, and entity data by health delivery organizations and others is suggested by Exhibit 3. Users will have access to the data they provide in the form in which they provide it, so that corrections can be made to erroneous entries. For example, providers will be able to modify records that they created on individual patients. Users also

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[3]Such services will include, at a minimum, inpatient hospital stays; outpatient visits to hospitals, clinics, physicians and other providers; procedures at ambulatory surgery centers; home health care visits; nursing home and other long term care services; prescription drugs; and other services covered under the guaranteed benefit package and under supplemental packages.

will have access to aggregate data of other organizations when the National Health Board determines that sharing such information is necessary or would improve the competitiveness of the health care system. For example, a health plan will need access to claims of individual patients for whom they are coordinating benefits with another plan. Users also will have access to disaggregated data of other organizations when those disaggregated data have privacy safeguards and when access to those data is authorized by the Data Protection and Security Panel. For example, national users such as researchers might be authorized to analyze encounter records but only with personal identifiers masked. Policies on access to data will ultimately be set by the National Health Board.

C. The Inefficiencies of a Decentralized Information System

The alternative to an integrated information system located at a few regional data centers and one coordinating data center is an information system distributed and situated locally. Proponents of a decentralized design are motivated by concerns that Federal access to a massive system of health records could jeopardize patient privacy and result in costly and burdensome micro-management of the health care system. A decentralized data system may or may not reduce these concerns. However, it raises other problems and has major consequences for the cost of the information system.

There are substantial economies of scale from managing such a system at 5 locations rather than distributing it among 50 to 500. A decentralized data system would require about 50 States, 100 alliances, and/or 500 plans to develop not only the capacity to support independently their own data requirements but also the ability to:

- manage numerous reporting requirements,
- handle standard and special requests for information, and
- coordinate their information systems with many other data organizations.

The savings of a regional system include the obvious staffing and computer resources that would not be required at local levels, as well as the spillover savings to users of health care data.

Wherever data are located, staff will be needed to:

- design each information system;
- oversee its construction;
- develop software for the information system, both for
  - transactions (such as claims and payments) and
  - analytic files (such as provider utilization);

- operate the system;
- provide data services to health care organizations for coordinating enrollment, benefits, payments, and other functions;
- handle hundreds (perhaps thousands) of special requests for data from other organizations; and
- provide technical assistance to data users.

In addition, significant computer purchases would be required for many health plans and States. Under health care reform, some health plans will have to automate manual systems; many will develop electronic data interchange capabilities for the first time; and most will expand computing capacity to save and process data in ways that they have never done before (e.g., building historical files, processing complete databases to identify special subsets, checking and cleaning data for multiple purposes, and producing analytic files for special reports and requests). States will vary tremendously in their need for new computing capacity. Even States with experience processing claims for the Medicaid program would see a seven-fold increase in the volume of claims that they would have to handle if they were a central source of data for the State. Nearly half of the States have no large transactions-type database experience with health data. It is likely that large mainframe computers would have to be purchased by many States, if an integrated information network were not available. Likewise, plans would have to expand their capacity to fulfill the information needs of health care reform.

In addition to staffing and computer costs, there are major spillover costs to users depending on the design of the information system. If the system is decentralized to the State or plan level, the cost of obtaining data for any purpose will be 50 or 500 times, respectively, the cost of obtaining it from one source. The likely result is that research by individual investigators will be stymied by the effort required to assemble data. Furthermore, even large organizations that will assemble data from multiple State or plan sources will differ in purpose, approach, and ability to use the data for other than their original purpose. Section II, on uses of the information system, reveals the breadth of potential uses of such information and the fact that databases assembled for one purpose are seldom sufficient for other uses.

There is ample evidence from the Medicaid program and from data systems of the Public Health Service that there is tremendous variability across the States in terms of technical capacity, resources for data systems, procedures for protecting data, and policies for releasing data. A clear lesson from the Medicaid program, which is still struggling to assemble a uniform national database of Medicaid claims, is that independent data centers will take varying approaches to collecting, screening, cleaning, and providing access to data. This lack of uniformity results in a very high cost of reconciling and assembling data from different sources. There is evidence from the Medicare program of how an integrated information system can keep administrative costs low and still provide data for many different purposes.

A centrally located health information system with standardized data security, collection, processing, and dissemination will assure consistent and efficient recordkeeping. It will do this by:

- ensuring uniformity in policies to protect patient privacy while allowing access to data for appropriate uses;
- avoiding the cost of coordinating hundreds of separate data encryption schemes for protecting data during transmission to and from the data centers;
- eliminating duplication in staffing and data processing and storage capacity that would arise with 50 or more decentralized systems;
- preventing the costs of reconciling different data handling conventions that always arise with distinct information systems;
- reducing delays in data submission that would occur with multiple data systems and multiple layers of data collection and transmission;
- lowering the cost of health statistics and health services research by providing data from one uniform source;
- providing access to information that can foster continuous quality improvement and gains in efficiency of health care services;
- lessening substantially the burdens on the plans, alliances, and States of filling the many and overlapping requests for health data;
- reducing substantially the challenge to many States (e.g., rural and poor States) of building new information systems where none now exist to comply with health care reform; and
- rectifying the inequalities across States that otherwise would exist in information because States have varying levels of resources, technical sophistication, and capacity to develop and support information systems.

A fully integrated information system will save hundreds of millions of dollars in the administrative overhead of information systems that States, alliances, and plans otherwise would have to incur.

II. Uses of the Information System

The health care information system will support many of the planning, management, and oversight responsibilities of the health care system. It also will support other health care reform requirements -- public health activities and research to improve medical care and the health care system.

Some of the functions requiring data will be served only by a database of *all health care encounters*. Others functions could be adequately served by a sample. However, many different types of samples would be required to fulfill all the needs for data from the health information system. This is because uses will differ in terms of the focus of the question, the subpopulations of interest, and the reliability required for inferences. One or even a few samples could never serve all of the requirements of management, research, and unexpected uses, as described below.

A. Health System Management

A health care information system will support many of the responsibilities of the National Health Board, the States, and regional and corporate health alliances. A health information system will also serve health plans, even though they will directly collect records of encounters within their plans. The information system will give plans the capacity to compare their performance (through aggregate statistics) to that of other plans and, thus, improve their competitiveness.

Seven functions of health system management can be effectively served by a health care data system:

- monitoring spending and developing budgets,
- establishing premiums and adjusting for risk,
- negotiating rates with providers,
- coordinating benefits among multiple insurers,
- monitoring performance and quality,
- providing consumer value information, and
- detecting fraud and abuse.

Most of these functions will either require or benefit substantially from access to an integrated information system with records on all enrollees, encounters, and organizational entities.

1. Monitoring Spending and Developing Budgets

Although national budgets will be set by the Federal government, monitoring of health spending and internal budgeting will occur at all levels of the health care system. The National Health Board will develop budgets related to each alliance and its spending under the guaranteed benefit package. These budgets will be based on average premiums of categories of enrollees and the number of enrollees in each category. The categories, yet to be defined, will relate to the risk of high medical expense.

Presently, no data exist for tallying enrollees and premiums by categories of risk for alliance budgets. Current estimates of national and state-level personal health spending are based on many different data sources and estimation methods; information for estimating levels of spending are incomplete for all States; and the normal one- or two-year delay in obtaining such data preclude its use for timely, accurate budgeting. No methods are presently available for tallying spending by geographic units below the State.

Eventually, the health information system will provide:

- complete and consistent reporting of enrollment and premiums for establishing or refining a base for national and alliance budgeting;
- an accounting of expenditures by components of the health care system (e.g., hospitals, physicians) so that compliance with expenditure limits can be assessed; and
- direct monitoring of changes in the volume of services that might occur because budgets of plans will be fixed and fee-for-service payments to providers will be limited.

Enrollment records could suffice for developing budget allocations at State and health alliance levels, but a complete database of encounter records will be required to evaluate compliance with expenditure limits down to the level of the provider.

2. Establishing Premiums and Adjusting for Risk

Even without a health information system, health plans will collect and use data on enrollment, benefits, utilization, and expenditures to establish premiums. They also will use these data to argue for risk adjustments or compensation for providing the guaranteed benefits to populations likely to have high medical expense.

Health alliances will require the same information as plans and could acquire it from the plans. However, the alliances will be strengthened by independent access to a complete information system. Given their crucial role as prudent buyer, such data will enable alliances to:

- judge the validity of plan's arguments for risk adjustments,
- compare risk across plans and even outside the alliance, and
- negotiate premiums and adjustments effectively.

Arrangements for risk pooling will succeed only if plans are compensated for absorbing true risks and are convinced that the risk classes, adjustments, and payments are fair. The more information that alliances have on the populations covered and on the patterns of utilization by service within each plan, the stronger their negotiating positions will be for constraining

premium increases for the guaranteed benefits. Access to the same data by all parties should streamline the negotiation process.

Alliances also will certify health plans. Comparative information on plans from the entity database will allow alliances to evaluate one plan against another.

A State agency will oversee the establishment of premium rates and adjustments and the certification of plans and alliances. Access to data on plans and alliances will help States streamline auditing processes. Computer searches can be used to target on-site audits of premiums and risk adjustments at little cost.

The National Health Board will be responsible for developing and improving risk adjustments methods that can be applied to data readily available within the health plans. Risk adjustment methods currently used by insurers are primitive. They rely on categories of age, sex, family size, geographic location, and a few high-cost diseases. Insurers calculate expected spending of their own enrolled population by these classes to establish premium differentials. The traditional categories of risk explain very little of the variation in expenditures across plans.

No national all-payer, all-service database exists in the U.S. for developing risk adjusters that will apply across plans and their distinct populations. Furthermore, no one can predict what kind of data may be essential for developing meaningful risk categories. We do know that large shares of medical expenditures typically result from small subsets of populations. This suggests that less than universal approaches to data collection could jeopardize the development of meaningful risk adjustment methods.

The history of Medicare's prospective payment system (PPS) for hospitals is a lesson in the importance of large databases for developing risk adjustments. The diagnosis related groups (DRGs) under PPS have been modified numerous times:

- to refine the categories;
- to narrow the variation in resource use within DRGs,
- to improve their measurement of severity of illness of patients,
- to extend their relevance to emerging medical technologies,
- to capture continual relative changes in treatments and settings, and
- to mitigate unfairness of payments across types of providers (e.g., too much for teaching hospitals, too little for rural hospitals).

Development of valid risk adjustment methods will require data from diverse health care settings, for various geographic locations; for thousands of clinical conditions; and for varied and specific subpopulations. Periodic

refinements of risk categories may be required for new areas of coverage and new methods of treatment that would be inadequately reflected in one or even a few national samples of records. A nation-wide database of all encounters can be used to determine the incidence, costs, and utilization related to new diseases and treatments, even if they are initially rare. Such a database can also be used to study whether and how best to revise classes for risk adjustments.

3. Negotiating Rates with Providers

Health plans will be negotiating contracts with providers of health care. Plans will have information from their own data systems on participating providers. However, without an integrated health information system, plans would not have data on health professionals affiliated with other plans. Nor would they have complete information on large health care institutions or individual providers who contract with multiple plans.

Full information within a market is one of the most effective methods of fostering competition. Plans will want to identify and contract with cost-effective providers of specific types of services and the plans will create incentives to encourage patients to choose those providers. The results will be:

- increased referrals to cost-effective providers,
- pressure on high-cost providers to lower prices and/or reduce inappropriate utilization, and
- increased economic specialization in medical care.

An system with information on capitated payments and charges and payments for fee-for-service arrangements will advance the economic efficiency of the health care market. It will:

- promote competition in local markets by efficiently providing the same information capacity in all local markets;
- stimulate regional "centers of excellence" (e.g., for hip replacements) by increasing referrals, spreading the high fixed cost of medical technology across more patients, and lowering the average cost of treatment;
- provide information about the cost-effectiveness of treatments provided in the national market (e.g., organ transplants and correction of congenital defects), which should steer patients to cost-effective health care teams; and
- serve all areas equally, whether or not they have the resources to develop an area-wide database system.

4. Coordinating Benefits among Multiple Insurers

The President's health care reform plan allows military dependents (and veterans) to choose between the Military Health Plan (Veterans Health Plan) and plans under the regional health alliance. The health care reform plan may also permit consumers to choose basic and supplemental benefits from different health plans. This means that payments for health services will need to be coordinated across health plans.

Currently, many insurers contribute data to the Medical Information Bureau, a compilation of information on individuals who have purchased or sought health insurance coverage from an insurer.[4] Through this database, participating insurers can usually determine whether individuals have multiple coverage and then coordinate payment of specific claims with other participating insurers. The database also includes information on suspected fraud.

The integrated information system under health care reform will provide information on all insurance plans in which individuals (or families) are enrolled. Such data, along with timely submission of claims and payments, will streamline and improve the coordination of benefits across multiple plans.

5. Monitoring Performance and Quality

Performance and quality will be monitored at all levels of the health care system. Health plans will monitor providers; alliances will monitor health plans; States will monitor alliances; and the National Health Board will monitor the States and other levels.

Performance and quality will be monitored across many dimensions:

- enrollment of the population,
- under-service or over-service of enrollees,
- appropriateness of diagnoses and treatments,
- outcomes of medical care, and
- costs of medical care.

Administrative encounter data can satisfy much of the need for performance and quality assurance measures. Many of the quality indicators proposed for quality assessments under health care reform can be produced from claims or encounter datasets. For example, indicators such as the rate of emergency room visits for pediatric asthma, the percent of females over 50 years of age

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[4]This database recently has been criticized publicly because individuals often cannot gain access to their own records.

receiving mammograms, the rate of admissions following ambulatory surgery could be assessed from encounter and enrollment records. Further, the complete encounter database will provide a complete sampling frame for disease-specific, outcome-based quality measures, such as ambulation after hip fracture.

Why not use samples? One sample of encounters might be sufficient for national or regional assessments. However, samples of increasing sizes would be necessary for evaluations at State, alliance, plan, and provider levels. A complete database is imperative for evaluating how different health care providers treat patients (possibly from different plans) with the same clinical conditions.

Comparison of a health plan's performance to national norms will require databases with the same types of information, coded in the same way for each health plan. Such comparisons will be facilitated by an integrated information system containing data that can be analyzed with consistent methods and aggregated by plan, across plans, and by type of service. Analyses based on separate databases of about 500 plans would increase the technical complexity and burden of monitoring plan performance and reporting.

The integrated information system will be useful to both alliances and plans. The alliances must use information on quality in their negotiations with plan, thereby giving alliances a strong incentive to query the database to identify differences between plans on quality measures. Plans will gain competitive advantages by using the database to assess and improve their performance relative to other plans.

A complete integrated information system also will support flexible and low-cost approaches for targeting more detailed quality review. Experience from Medicare's Peer Review Organizations suggests that rigid sampling protocols (e.g., targeting diseases and treatments and selecting patients by specific digits of their Social Security Numbers) may be susceptible to gaming by providers. Variable sampling criteria are important to give all providers a significant likelihood of scrutiny and all patients an equal chance of selection. Variable sampling criteria can be implemented and modified easily only if a census of records is available.

6. Providing Consumer Value Information

Health alliances will be responsible for providing consumers with information for choosing among health plans on the basis of:

- services covered (supplementary and guaranteed benefits),
- access of enrollees to health services,
- costs of comparable benefits, and
- quality of services delivered by the plan.

A complete information system will provide a comparable source of data for all health plans and all providers in the country. It will make possible report cards on plans and providers that are standardized and comparable across locales, as required by the President's health care reform plan. At the same time, health plans can customize measures and reports for their own enrollees, with user-friendly network software. A standard health care report card will facilitate comparisons nation-wide and at all levels of management and oversight. Armed with this information, patients can query their providers about the quality of their care. Plans and providers can use standard reports to evaluate their own performance and quality of care compared to others.

7. Detecting Fraud and Abuse

The National Health Board or its agent will be responsible for monitoring the health care system for fraud and abuse. Under fixed health care budgets, all sectors of the health care system will have an incentive to guard against fraud and abuse because it will ultimately limit the ability of the system to provide needed services. Health plans will be particularly vigilant because fraudulent claims will reduce their profits.

A complete health information system will be a critical source of information for identifying fraud and abuse based on:

- excessive billings for drugs, laboratory tests, physicians, or other services,
- excessive claims by one provider spread across multiple plans but not suspicious under any one plan,
- duplication of claims to primary and secondary payers, and
- veracity of plans' promotional materials concerning cost and quality.

A complete accounting of services by all providers offers investigators:

- a way to identify potential instances of fraud and abuse,
- a cost-effective source of evidence to support subpoena of more detailed records, and
- a complete body of evidence for court arguments.

A complete system of records is essential for identifying the rare but costly instances of fraud and abuse by particular providers or patients for particular services.

B. Public Health and Research

A broad array of public health and research activities will be possible with an integrated health care information system of enrollment, encounter, and entity records. Examples of these activities are:

- public health and epidemiologic surveillance,
- program evaluation,
- survey research, and
- medical effectiveness and outcomes research.

1. Public Health and Epidemiologic Surveillance

A complete health information system can be used to enhance the efficiency and effectiveness of public health activities and to target areas for epidemiologic investigations. Such data in conjunction with other surveillance methods can be used to:

- identify outbreaks of infectious disease (e.g., tuberculosis);
- track reportable health conditions (e.g., AIDS);
- provide early warning of local health hazards (e.g., Love Canal);
- monitor progress toward achieving Year 2000 Objectives such as those related to:
  - nonfatal head and spinal cord injuries,
  - hip fractures among the elderly,
  - hospitalizations for treatable conditions (e.g., asthma),
  - vaccine-preventable disease (e.g., pertussis, rubella),
  - use of preventive services (e.g., mammograms, Pap smears);
- identify adverse outcomes of medical devices and drugs (e.g., the health consequences of silicone breast implants);
- monitor safety and efficacy after fast-track approval by the Food and Drug Administration of drugs for fatal illnesses (e.g., AZT for AIDS); and
- supplement existing disease and treatment registries (e.g., the Surveillance, Epidemiology, and End Results (SEER) program).

Nearly all of these activities require 100 percent of records. The Centers for Disease Control and Prevention is currently trying to collect hospital discharge data to help identify the incidence of birth defects but has been hampered by the lack of a nation-wide database.

2. Program Evaluation

Future evaluation activities will focus on the impact of reform on the access to and the quality and cost of health care. While samples of enrollment and encounter records would provide the ability to evaluate access, quality, and cost on broad national or regional bases, a complete information system will support many different assessments, such as:

- **the effects of universal coverage on access by special subpopulations** (e.g., rural, inner city, minority, and under-served groups at the national or local levels);

- **the impact of reform on health expenditures and quality of care of specific providers** (e.g., teaching institutions, community hospitals, physician, dentists, and other health professionals);

- **the impact of including specific services in the guaranteed benefit package** (e.g., the cost and utilization of specific mental health benefits; the use and effectiveness of particular preventive services; the impact of covering higher-cost, brand-name prescription drugs; the effect of covering the routine care of patients enrolled in clinical trials; the cost of covered and proposed long-term-care services);

- **the impact of reform on employers** (e.g., employment effects, payroll effects of small versus large employers; the premium differences between regional and corporate alliances, the administrative costs of corporate alliances);

- **the influence of the supplemental insurance market** (e.g., whether or how it extends services or financial protection, increases utilization of services under the guaranteed benefit package, covers discretionary or essential services, or creates a two-tiered health care market for some essential services);

- **the effects of unprecedented expansions of managed care** (e.g., in restraining cost increases, maintaining quality of care, ensuring continuity of health care providers, gate-keeping for specialty services, and controlling out-of-plan utilization);

- **the effectiveness of the alliances in constraining health care costs** (e.g., competitive bidding versus allocated budgets, the importance of governance, and the effect of alternative management arrangements);

- **the results of unique State experiments in health care reform**, which currently include:

  - Florida's voluntary reform with cooperative purchasing arrangements,

  - Hawaii's employer mandate without managed competition,

  - Maryland's rate setting for physician services,

- Minnesota's small group and individual insurance market reform,

- New York's pure community rating and electronic clearinghouse project for eligibility determination, claims submission, coordination of benefits, and electronic payments,

- Oregon's "pay or play" plan, if voluntary incentives for covering the uninsured fail,

- Tennessee's plan to put Medicaid recipients and the uninsured into managed care,

- Vermont's global budget and, perhaps, a single-payer system,

- Washington's comprehensive reform, which most resembles the proposed American Health Security Act;

- **the diffusion of medical practice guidelines** (e.g., the early and late adopters of clinical guidelines, the successes and failures of guideline dissemination strategies, the usefulness of guidelines in reducing practice variation and lowering malpractice claims and awards); and

- **the diffusion and effectiveness of innovative and costly medical technologies** (e.g., bone marrow transplants for solid tumors).

3. Survey Research

Some aspects of the health care system can only be assessed from outside the system. Survey research will be required to assess:

- the success of the system in guaranteeing universal, uniform access to all eligible U.S. residents,

- the satisfaction of consumers with access to health services within the new health care system;

- trends in the health practices and health status of the U.S. population before and after health care reform; and

- the functional status of patients and their health outcomes following specific treatments.

The cost of survey research can be reduced by the availability of a complete information system including enrollment, encounter, and entity records. Survey research costs will decline because much of the preparatory field work -- enumerating housing units and screening them for eligible respondents -- can be eliminated and information substituted from the complete, integrated health information system. With a mechanism for linking masked health records back to individuals and approval of the National Health Board, the information system could be used:

- as a sampling frame for national probability samples and
- as a basis for identifying specific subgroups for over-sampling, based on their utilization experience or other characteristics.

Furthermore, as uniform data become available on health care utilization and expenditures and on plan and provider characteristics, expensive personal interviews on health care expenditures and abstractions of complicated administrative records will not be necessary.

4. Effectiveness and Outcomes Research

Very large databases are required for medical effectiveness and outcomes research designed to improve the practice of medicine. Size is important to:

- guarantee the statistical power to detect clinically significant differences, and
- ensure that conclusions can be generalized to the population at large.

The size of the database is key to studies that focus on:

- infrequent, but expensive, therapies (e.g., bone marrow transplantation);
- frequent (and therefore costly) treatments with low rates of adverse outcomes (e.g., cholecystectomy);
- outcomes of specific medical interventions (e.g., prostatectomy for prostatic hyperplasia);
- alternative treatments for specific conditions (e.g., hysterectomy versus watchful waiting for uterine fibroid cysts);
- small area variations (e.g., across counties, cities, zip codes, or medical market areas);
- variations in practice by individual providers (e.g., across hospitals, physicians, or other health professionals);
- development of practice guidelines (e.g., for chronic low back pain);
- evaluation of the effect of guidelines on the practice of medicine (e.g., use of analgesics pre- and post-dissemination of the post-surgical pain management guideline).

C. Planning for the Unexpected

No one can predict all the uses that a health care information system might serve. The Hospital Cost and Utilization Project (HCUP), which is an AHCPR database that includes 100 percent of discharge records from a large sample of U.S. hospitals, was initiated in the 1970s to study cost inflation in the hospital sector controlling for the product mix of the institution. Since then, it has been used to:

- study the response of hospitals to Medicare prospective payment,
- evaluate and develop patient classification systems,
- study the hospital costs and financing of the AIDS epidemic,
- explore access to specific hospital services by under-served populations,
- understand the patterns of diffusion of medical technologies, and
- develop priorities for medical effectiveness research.

Currently, HCUP is being used (at the suggestion of the Office of Management and Budget) to investigate the effects of voluntary global budgeting among hospitals in Monroe County (Rochester), New York in order to anticipate responses to global budgets under health care reform.

Not one of these additional uses was anticipated when HCUP was conceived. Many of these additional uses would not have been possible without a complete database of 100 percent of discharges from HCUP hospitals. Clearly, administrative data collected for one purpose can be invaluable for studying health policy questions yet to emerge.

Unplanned uses of a database of all encounter records under the new health care system may involve:

- specific or narrow refinements of the reformed health care system,
- policy initiatives to solve as yet undiscovered problems of health care delivery,
- improvements in the efficiency of treating medical conditions by providing feedback to health care providers with excessive costs or utilization,
- timely scientific evaluation of new medical treatments, and
- the need for outreach or other initiatives for special populations.

Futurists speak of the information age that is fast approaching. Already innovators are developing the computerized patient record; digital storage, transmission, and retrieval of radiologic exams; standards for data transmission that open medical consultation via telecommunication; computer-assisted medical decision-making; and interactive computer programs to inform patients and increase their participation in treatment decisions. Indeed, the Medicare drug benefit program proposed in the American Health Security Act mandates capture of drug claims in a national network for feedback to pharmacies. Pharmacies would then use the network to monitor patient drug usage and potential adverse drug interactions. Developments in these areas might eventually expand the usefulness of enrollment and encounter data in providing:

- identification of patients meeting the rigid clinical requirements for specific clinical trials, thus, speeding the accrual of patients and improving the ability to generalize findings of clinical trials;

- streamlined collection of vital records of births and deaths, improvements in recording causes of death, and linkages of deaths with treatment histories to validate death certificate information and better understand outcomes of treatments; and

- combination of treatment histories and autopsy reports on a large scale to better understand the outcomes of specific surgical and medical interventions.

A systematic, integrated information system will open opportunities for studies that will advance medical practice, as well as improve the organization and delivery of care, and ultimately the health of the population. A complete, integrated information system also will reduce the need for expensive and overlapping individual data collection activities as new health care issues emerge.

III. Conclusion

Individually and collectively, this paper points to the many and varied benefits of a complete integrated health care information system that includes all patient contacts with the health care system. Such a data system is needed to support administrative functions under the new health care system and can support epidemiologic and research functions as well.

A less than universal approach to data collection would represent a false economy and would undoubtedly result in higher costs to providers, plans, alliances, and States. Placing the burden of responding to requests from numerous organizations on these data sources would raise the administrative costs associated with data management under health care reform. This would occur because:

- The uses for data, listed above, represent not one but potentially thousands of requests each year.

- It is nearly always less costly for data sources to provide all encounters than it is for them to provide a special extraction.[5]

An integrated information system of all U.S. health system encounters will support a wide variety of uses. In general, such a database will:

- improve significantly the critical functions of managing the health care system such as monitoring provider and health plan performance, assessing the quality of health care, and detecting fraud and abuse;

- provide a central authority for establishing procedures to protect the privacy of individual records which is now done with varying effectiveness under separate State statutes;

- ensure flexibility for drawing samples for varying purposes at the lowest possible cost;

- equalize resources, capacity, and access to information across States and localities; and

- provide a public good that all components of the system would use in a more competitive health care system.

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[5]This has been found in development of the national sample databases of the Healthcare Cost and Utilization Project and the National Hospital Discharge Survey. [NCHS: Is this true for NHDS too?]

File

THE WHITE HOUSE

WASHINGTON

November 3, 1993

Roger Harlan
Tuscon HIV/AIDS Care Consortium
6601 East Grant Road, Suite 111
Tuscon, AZ 95715

Dear Mr. Harlan:

Thank you so much for asking me to participate in Arizona's first ever statewide HIV/AIDS conference. Unfortunately, my schedule prevents me from attending but I have prepared a videotape message for your participants. As I state in my message, local and federal partnerships are critical to meeting the national AIDS agenda, which is to stop the AIDS epidemic. Thank you for your work in this area.

Best wishes with your conference.

Sincerely,

Kristine M. Gebbie /s/
Kristine M. Gebbie
National AIDS Policy Coordinator

Enclosure

2:15 C 11/1

Tucson Community Foundation

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FAX

DATE:	September 29, 1993
TIME SENT:	2:30 pm
TOTAL PAGES (including Cover Page)	2
FROM:	Roger Harlan
SENT TO:	Buck Buckingham Office of the AIDS Policy Coordinator AIDS Partnership
FAX NUMBER:	(202) 632-1096

COMMENTS:

Yes, we would like to have Kristine Gebbie do a video-taped welcome. Attached are some suggestions. Please call me if there you need any information particular to Arizona or the Forum.

Thank you.

Tucson HIV/AIDS Care Consortium

The Tucson Community Foundation and the National Community AIDS Partnership

DATE: September 29, 1993

TO: Buck Buckingham, Office of the AIDS Policy Coordinator

FROM: Roger Harlan Roger Harlan

Thank you for the suggestion of a video message from Kristine Gebbie. It's a great idea. We're disappointed that neither Ms. Gebbie nor you will be able to attend; however, such a videotape might be a very effective means to reinforce the role of community-based organizations in influencing state and national policy.

I suggest a 5-minute video message that can be shown early in the day to help set the tone for what we want to accomplish. I'm including a draft of the day's agenda so you see the topics that will be addressed. The following are some talking points that might be included in the message:

- This is the first statewide effort joining together Pima and Maricopa counties, as well as the outlying rural counties, in addressing public policy at the state and local level. NCAP sees this Forum as the first phase of a process to build our capacity to affect public policy decisions.
- One thing that unites us all is that everyone participating here today has the ability and the motivation to effect change. Local voices can help to move the agenda at the state and federal level.
- Our statewide cooperative effort lends power to our voice as we begin to work with state and national agencies and legislators.
- This Forum has attracted the wide spectrum of persons involved with HIV/AIDS--including health care workers, agency heads, legislators, urban and rural representatives, persons from Arizona's Hispanic, African-American, and Native American communities, and many persons who are most directly affected by this health crisis: people living with AIDS.
- Might discuss the national priorities as initially envisioned by the Office of the AIDS Policy Coordinator. How can we at the local level assist?

If there is additional information we can provide, please give me a call. Thank you.

F:PP-GEB

John—

9/30/93

Please handle this
for me/them. Many
thanks. Bruce

SEP 30 1993

Tucson Community Foundation

6601 East Grant Rd., Suite 111 Tucson, Arizona 85715 (602) 722-1707 FAX: (602) 296-2387

FAX

DATE:	September ~~29~~ 30, 1993
TIME SENT:	~~2:30 pm~~ 8:20 a.m.
TOTAL PAGES (including Cover Page)	~~2~~5
FROM:	Roger Harlan
SENT TO:	Buck Buckingham Office of the AIDS Policy Coordinator AIDS Partnership
FAX NUMBER:	(202) 632-1096

10/4 Leave request. Script plan

COMMENTS:

Yes, we would like to have Kristine Gebbie do a video-taped welcome. Attached are some suggestions. Please call me if there you need any information particular to Arizona or the Forum.

Thank you.

We forgot to send the agenda. Sorry.

AGENDA

DRAFT

ARIZONA COMMUNITY FOUNDATION
Maricopa County Community AIDS Partnership
TUCSON COMMUNITY FOUNDATION
Tucson HIV/AIDS Care Consortium
NATIONAL COMMUNITY AIDS PARTNERSHIP
PUBLIC POLICY FORUM

ARIZONANS IN PARTNERSHIP:
ONE VOICE FOR HIV/AIDS POLICY REFORM

Friday, November 5, 1993
ASU Downtown Center, 502 E. Monroe Street
Phoenix, Arizona

8:00 - 9:00 **REGISTRATION**

9:00 - 9:15 **WELCOME**
ACF Representative
TCF Representative

9:15 - 9:45 **KEYNOTE ADDRESS**
Objectives: Set the stage for the day; Discuss emerging prevention, education, and service delivery needs as they are being addressed at national level; Stress the importance of local organizations in shaping policy and what needs to be done at grassroots level.

9:45 - 10:30 **PLENARY**: Overview of state and federal HIV/AIDS picture
Introduction by Kirk Baxter, Phoenix Body Positive

Dr. Bob England, AZ Dept. of Health Services, Phoenix
Karen Ringen, AIDS Action Council, Washington, DC

Objectives: Present update of what is happening at state and national level; Topics might include brief statistical update, current or possible legislation, and two or three cutting-edge issues. What are the critical policy issues at both levels?

10:30 - 10:45 **BREAK**

10:45 - 12:15 **GENERAL SESSION** - All Attend
Advocacy: The Nuts and Bolts
Moderator: Sandra McDonald - President, OUTREACH, Inc., Atlanta, GA

ACLU Representative (Lewis Rhodes or Other person) or Nora Montanez, Women Street Support Center, Phoenix
Isabel Garcia, (lawyer) Tucson
U.S. Rep. Karan English, District 6, Flagstaff (or State Sen. Cindy Resnick,

District 14, Tucson)
Marian Banzhaf, NJWAN, New Brunswick, NJ

Objectives: Session should start at the beginning: What is "public policy" and what is its connection with rule-making, legislation and simple wishful thinking? How are rules or legislation changed? Presenters should describe effective models for advocacy; what has worked for them and what were the steps in achieving their goals; what should someone look for when barriers are presented.

12:15 - 1:30 **LUNCH**

1:30 - 3:30 **WORKSHOPS** (Choose one)

Overall objectives: Each workshop should be interactive; Presenters will give brief presentations and then hear from participants about the unmet needs they feel are most important under the workshop topic; Presenters will strive for consensus on prioritizing these needs and move directly into a discussion on developing public policy/advocacy strategies to address these needs through policy change; An assigned reporter will take notes and be prepared to report out on one or two of these strategies at Closing Session; Moderator should make sure participants discuss specific policy/advocacy strategies needed to meet unmet needs instead of identifying more needs.

I. AHCCCS, Subsidized Care and HIV/AIDS

Moderator: Steve Trujillo, Co-chair, Tucson HIV/AIDS Care Consortium

Linda Redman, Deputy Director, AHCCCS, Phoenix
Sen. Cindy Resnick, District 14, Tucson (or Rep. Susan Gerard, District 18, Phoenix)
Dr. Kevin Carmichael, University Family Care, Tucson
Dr. Leonard Ditmanson, Kino Community Hospital, Tucson
Denise (DeeDee) Peterson, Cochise County Dept. of Health and Social Services, Bisbee
Rev. Bill Tye, Tempe

Reporter: Gloria J. Valenzuela, Project Hacer, Tucson

Objectives: Presenters will focus on the AHCCCS managed care/cost containment system. What makes HIV/AIDS disease needs unique in a managed care system? How does AHCCCS function differently in urban and rural areas? What are the barriers in accessing the system for an HIV+ person? What are specific policy areas in AHCCCS that are problematic for HIV disease (spend-down, auto assign, provider education, etc.)? Based on identified areas, what are one or two strategies for changing AHCCCS?

II. Coordinated Planning for HIV/AIDS Support Services
Moderator: Doug Hirano, AZ Dept. of Health Services

David Paquette, AZ Dept. of Health Services, Phoenix
Jan Kenney, Arizona Community Foundation, Phoenix
Becky Smith, Yuma County Dept. of Health, Yuma
Robert Gomez, El Rio Santa Cruz Health Center, Tucson
Steven Englender, Maricopa County Health Department, Phoenix
Bruce Porter, Tucson AIDS Project, Tucson
John Wilson, Navajo Nation Social Hygiene Branch, Gallup, NM

Reporter: Robbie Bergman, AIDS Outreach, Flagstaff

Objectives: Panel will focus on how the allocation of resources for HIV/AIDS can better reflect coordinated planning by governmental/private entities; emphasis on role of government/private entities in providing for the continuum of care, and avoiding duplicating services.

III. HIV/AIDS and Youth
Moderator: Ruth Grove, AZ Dept. of Education

Diane Ogilvie Crose, Manager of Community Education, Planned Parenthood of Central and Northern Arizona, Phoenix
_____, Wingspan (adult who runs gay youth program ?), Tucson
Mary Halter, Consultant, Phoenix
Kimbal Babcock, _____, Flagstaff
Jason Cuneo, Member of Students for the Prevention of AIDS (SPA), Tucson
_____, (Rural minority youth identified by Terry Mendez)

Reporter: Chris Brown, Pima County Health Dept., Tucson

Objectives: Educate participants on the following: State guidelines on sex education and HIV/AIDS mandates; Utilizing agencies that have outreach programs to youth; Areas that have been neglected in education programs (i.e., discussion of sexual orientation, use of condoms) for youth; Substance abuse and STDs as risk factors; Disenfranchized youth.

IV. HIV/AIDS and Culturally Diverse Community Issues
Moderator: Guillermina Contreras-Arriola, University of Arizona Mt. States Regional Hemophilia Center, Tucson

Carlos Velez, Office of the AIDS Policy Coordinator, Washington, D.C.
Debra Toya, AIDS OUTREACH, Flagstaff
Rep. Herschella Horton, District 14, Tucson

Ramon Garcia, Cochise County Dept. of Health, Bisbee
Enrique Gomez, El Proyecto Arizona-Sonora, Tucson
Kathy Torres-Paddock, TERROS, Phoenix

Reporter: Agatha Chavarria, Yuma County WATTEC, Yuma

Objectives: Panel will create an awareness of the problems that specifically confront HIV+ ethnic minority populations. Those issues might include: cultural competence, economic issues, substance abuse among minority communities, adequate or equal access to health care, special problems in reaching those communities.

3:30 - 3:45 **BREAK**

3:45 - 4:45 **CLOSING SESSION**
Moderator: Ron Barber, Co-chair, Tucson HIV/AIDS Care Consortium
Reporters: Gloria J. Valenzuela, Tucson
Robbie Bergman, Flagstaff
Chris Brown, Tucson
Agatha Chavarria, Yuma

Objectives: Provide an interactive dialogue. The reporter from each session will give a 5-minute report on one or two key strategies identified in her/his workshop; After each report, the moderator will encourage the panelists to respond and comment; After all four workshop strategy reports have been presented and discussed, the moderator will open up to the audience for Q&A for the remaining time.

4:45 - 5:00 **CLOSING REMARKS -- CALL TO ACTION**

George Lusk, Consultant, Phoenix

Objectives: Move directly from the report discussion to a call-to-action; Restate the strategies identified during the report presentation and present to the participants for their ideas about ways to implement these strategies in their community, i.e., next steps towards influencing development of public policy.

Tucson Community Foundation

6601 East Grant Rd., Suite 111 Tucson, Arizona 85715 (602) 722-1707 FAX: (602) 296-2387

FAX

DATE:	October 4, 1993
TIME SENT:	10:10 am
TOTAL PAGES (including Cover Page)	2
FROM:	Roger Harlan
SENT TO:	John Gurrola Office of the AIDS Policy Coordinator
FAX NUMBER:	(202) 632-1096

COMMENTS:

This is the list of suggested talking points that I sent to Buck. Let me know if there is anything further we can provide.

Tucson HIV/AIDS Care Consortium

The Tucson Community Foundation and the National Community AIDS Partnership

DATE: September 29, 1993

TO: Buck Buckingham, Office of the AIDS Policy Coordinator

FROM: Roger Harlan Roger Harlan

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- Might discuss the national priorities as initially envisioned by the Office of the AIDS Policy Coordinator. How can we at the local level assist?

If there is additional information we can provide, please give me a call. Thank you.

F:PP-GEB

welcome

Importance of statewide mtg -
- inclusion of rural folks
- inclusion of all populations

Nat'l Priority -
- more research agenda
- care / health reform
- prevention
- reshaping debate nationally -

THE WHITE HOUSE

WASHINGTON

November 3, 1993

MEMORANDUM

TO: Clif Gaus

FROM: Kristine M. Gebbie W. Steve Lee for
National AIDS Policy Coordinator

SUBJECT: DHHS information systems

I have reviewed the draft The U.S. Health Care Information System: Design and Use Under Health Care Reform. Sorry, I'm slow in getting you comments, but I would suggest adding the following:

> Page 2: Existing state and national protection for records associated with conditions such as HIV infection, AIDS and substance abuse treatment may need to be revised under the new system. Any revisions must take into account the need for protection from disclosure and prevention of discrimination against vulnerable individuals.

Thanks -- this is a great step in explaining the planned system.

THE WHITE HOUSE

WASHINGTON

November 3, 1993

MEMORANDUM

TO: Dr. Phillip Lee
Assistant Secretary for Health

FROM: Kristine M. Gebbie W. Steinhe for
National AIDS Policy Coordinator

SUBJECT: HIV Management Guidelines

The AHCPR has shared with me the recently completed Guidelines for Evaluation and Management of Early HIV Infection. I have reviewed the materials. While I provided a couple of possible edits to Dr. Clinton, the document as it now stands is appropriate for release. I hope publication and release to practitioners can happen quickly. It is clear and to the point on an area of HIV care in which more and more practitioners across the country are involved.

Please let me know if I can help this process along.

cc: Dr. Jarrett Clinton

THE WHITE HOUSE

WASHINGTON

November 4, 1993

Sandy Thurman, Manager
Task Force on Child Survival and Development
The Carter Center
One Copenhill
Atlanta, GA 30307

Dear Sandy:

Thank you for joining other members of the CAEAR Coalition in meeting with me. It was good seeing those of you whom I already knew and meeting so many others as well. I especially appreciated the first-hand examples of effective Title I planning and service delivery that you shared.

I look forward to working closely with you on securing adequate levels of funding for the Ryan White Care Act and on the various issues surrounding re-authorization of the Act.

Sincerely,

Kristine Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 4, 1993

Judith Johns
Assistant Commissioner for HIV/AIDS
Chicago Department of Health
50 West Washington Street, Room 233S
Chicago, IL 60602

Dear Judith:

Thank you for joining other members of the CAEAR Coalition in meeting with me. It was good seeing those of you whom I already knew and meeting so many others as well. I especially appreciated the first-hand examples of effective Title I planning and service delivery that you shared.

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Sincerely,

Kristine Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 4, 1993

Bob Wood, M.D.
AIDS Prevention Project
2124 Fourth Avenue, Fourth Floor
Seattle, WA 98121

Dear Bob:

Thank you for joining other members of the CAEAR Coalition in meeting with me. It was good seeing those of you whom I already knew and meeting so many others as well. I especially appreciated the first-hand examples of effective Title I planning and service delivery that you shared.

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Sincerely,

Kristine Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 4, 1993

Todd Summers
AIDS Housing Corporation
95 Berkeley Street, Suite 619
Boston, MA 02116

Dear Todd:

Thank you for joining other members of the CAEAR Coalition in meeting with me. It was good seeing those of you whom I already knew and meeting so many others as well. I especially appreciated the first-hand examples of effective Title I planning and service delivery that you shared.

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Sincerely,

Kristine Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 4, 1993

Judy Moore-Nichols
HIV/AIDS Program Manager
Kansas City, Missouri Health Department
Co-Facilitator
Kansas City Ryan White CARE Consortium
1423 East Linwood
Kansas City, MO 64109

Dear Judy:

Thank you for joining other members of the CAEAR Coalition in meeting with me. It was good seeing those of you whom I already knew and meeting so many others as well. I especially appreciated the first-hand examples of effective Title I planning and service delivery that you shared.

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Sincerely,

Kristine Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 4, 1993

Chuck Kuehn
Director
Tampa AIDS Network
11215 North Nebraska Avenue, suite B-3
Tampa, FL 33162

Dear Chuck:

Thank you for joining other members of the CAEAR Coalition in meeting with me. It was good seeing those of you whom I already knew and meeting so many others as well. I especially appreciated the first-hand examples of effective Title I planning and service delivery that you shared.

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Sincerely,

Kristine Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 4, 1993

Mike Shriver
Executive Director
Mobilization Against AIDS
1540 Market Street, Suite 160
San Francisco, CA 94102

Dear Mike:

Thank you for joining other members of the CAEAR Coalition in meeting with me. It was good seeing those of you whom I already knew and meeting so many others as well. I especially appreciated the first-hand examples of effective Title I planning and service delivery that you shared.

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Kristine Gebbie, RN, MN
National AIDS Policy Coordinator

THE SHERIDAN GROUP

Government and Public Relations

Attendees of Meeting with Kristine Gebbie

Judith Johns
Assistant Commissioner for HIV/AIDS
Chicago Department of Health
50 West Washington Street, Room 233S
Chicago, IL 60602

sheridan. let

thank you
letters - boiler
plate for address
list.

Chuck Kuehn
Director
Tampa AIDS Network
11215 North Nebraska Avenue
Suite B-3
Tampa, FL 33612

Judy Moore-Nichols
HIV/AIDS Program Manager
Kansas City, Missouri Health Department
Co-Facilitator
Kansas City Ryan White CARE Consortium
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One Copenhill
Atlanta, GA 30307

Bob Wood, M.D.
AIDS Prevention Project
2124 Fourth Avenue, Fourth Floor
Seattle, WA 98121

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Ms. Audra Carter-Wilkins
Marketing and Concepts
37817 Boxthorn Street
Los Angeles, CA 93552

Dear Ms. Carter-Wilkins:

Thank you for participating in the meeting in Los Angeles on Tuesday evening, October 26. I appreciate the opportunity to meet some of those working on HIV/AIDS issues in Los Angeles. Please stay in touch as issues, concerns or opportunities arise.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Ms. Shannon Broch
811 Westhimer
Houston, Texas 77006

Dear Ms. Broch:

I just learned of the enclosed newsletter being developed by a young woman living with HIV. I thought you might find it of interest.

I've thought of you often since our meeting last summer, and hope things are going well.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Enclosure

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Mr. Brian Jackson
2232 S. 99th E. Avenue, #47B
Tulsa, Oklahoma 74129

Dear Mr. Jackson:

I just learned of the enclosed newsletter being developed by a young woman living with HIV. I thought you might find it of interest.

I've thought of you often since our meeting last summer, and hope things are going well.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Enclosure

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Mr. Matthew Robertson
1501 Bayard #9
Houston, Texas 77006

Dear Mr. Robertson:

I just learned of the enclosed newsletter being developed by a young woman living with HIV. I thought you might find it of interest.

I've thought of you often since our meeting last summer, and hope things are going well.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Enclosure

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Ms. Lillie M. Gillespie
209 Silver Street
Hot Springs, Arkansas 71901

Dear Ms. Gillespie:

I just learned of the enclosed newsletter being developed by a young woman living with HIV. I thought you might find it of interest.

I've thought of you often since our meeting last summer, and hope things are going well.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Enclosure

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Ms. Juanita Hernandez
Route 16, Box 213107-13
Santa Fe, New Mexico 87505

Dear Ms. Hernandez:

I just learned of the enclosed newsletter being developed by a young woman living with HIV. I thought you might find it of interest.

I've thought of you often since our meeting last summer, and hope things are going well.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Enclosure

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Mr. Chad J. Courson
222 Barton Street
Little Rock, Arkansas 72205

Dear ~~Mr. Courson~~ Chad:

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I've thought of you often since our meeting last summer, and hope things are going well.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Enclosure

R E A L I T Y

A Newsletter By and For Youth Living with HIV

Introduction *by Antigone Hodgins*

Hello and welcome to **REALITY** (**REAL** Ideas and Thoughts by and for Youth). My name is Antigone Hodgins and I am an young woman living with HIV Disease. I was twenty-two years old when I tested and I am now twenty-four. I work at Project AHEAD, in San Francisco and coordinate a Speaker's Bureau of other young people who are HIV+ or who have AIDS. I also have had the opportunity to create this newsletter.

When I first tested, I felt alone, scared and most of all, helpless. HIV took away my self-esteem and any hope I had that I was going to live a happy and long life.

During the first three months after I got tested, I was overwhelmed by my fears and it felt like there was going to be no way out. Various people I have met since then have served as guiding lights to help me take the path that I have chosen. One place that has helped light a path for me is a group called BAY Positives (Bay Area Young Positives, a support group for youth 25 years and younger who are HIV+). This was the first place that showed me that I was not alone. I met other young people who were living healthy, productive lives. I realized that there was hope and there was *cont'd pg. 2*

Before and After *by Justin Early*

I am not sure how to start this so here goes it...I am a dope fiend. I started shooting cocaine and heroin at 10 years old and didn't stop until I was 21. I grew up in the streets, surviving through prostitution and illegal acts, i.e. robbery, burglary, theft, etc. I didn't know how to be "normal". All I knew how to do was survive and use drugs and alcohol.

In August of 1989, I was fed up with using and going to jail so I moved to San Francisco from Seattle, Washington. I did alright until I got hooked on the dope again and then it was down hill from there. The next thing I knew, I was in jail again for drug charges. I was a fucking mess. I had NO friends because they knew I would steal from them (and I would). I had no morals and cared about nothing and no one. I was a selfish junkie.

In April of 1991, I shot some bad dope and ended up in the hospital with endocarditis, cellulitis and a big abscess on my ankle. Scott Walker came to see me. I didn't know him, nor did I want to. After a while I know he cared and I trusted him. He suggested that I get tested for the HIV virus. So I did. I ended up getting kicked out of the hospital for flicking a lit cigarette in a nurses face and missed the appointment to get my results.

"He suggested that I get tested for the HIV virus."

Eventually I got my results and I came back positive. FEAR went through my body because this was never going to happen to me. Not Justin. But it did. *cont'd pg. 3*

TABLE OF CONTENTS

y o u t h f o r y o u t h

you are not alone

something I could do to fight this awful disease. BAY Positives was founded by Julie Graham and Scott Walker in 1989. Without them I wouldn't be where I am today.

One reason why I thought REALITY was something that needed to happen was because of what I learned from Rebecca Dennison, an HIV infected woman, who created WORLD (Women Organized to respond to Life Threatening Diseases, a newsletter by and for HIV+ women). WORLD showed me how powerful a newsletter could be. Rebecca Dennison planted a seed and a whole new community of women have united as a result of her dedication and conviction.

It is now time for youth to be seen and acknowledged. This newsletter is a place to be seen, heard and valued. As a common voice we can be strong. As a community our issues are different and unique. We are still becoming infected and some of us are dying of AIDS. But we are not giving up and I believe that all of our lives have meaning.

Thank you Ron Henderson and Janet Shalwitz (Special Programs for Youth), your trust in me, your eagerness and guidance have been the foundation to making this happen.

Please come join us in this fight, we need you, each new voice makes the last one even more powerful!!!

Please mail in your letters, stories, poems, thoughts, ideas and experiences. And we will publish them.

THANK YOU!!!!!!!!!!

SUPPORT IN SAN FRANCISCO

BAY POSITIVES

Support grcups for young men and women with HIV 25 years and under. Call: Julie Graham 415/824-2726

COLE STREET CLINIC

Medical and support services for youth 23 and under. Call: 415/751-8181. Located at 555 Cole Street - #5 at Haight

LARKIN STREET YOUTH SERVICES

Medical support and housing services for homeless and runaway youth, 13 to 23yrs. old. Call: 415/673-0911. Located at 1044 Larkin St.

SAN FRANCISCO GENERAL HOSPITAL

Medical and support services for youth 21 and under. Call: Ellen Moore 415/206-8436 .

18TH STREET SERVICES

Alcohol and substance abuse outpatient recovery services for HIV+ youth. Call: James Kennedy 415/861-4898. Located at 217 Church Street at Market Street.

BAYVIEW HUNTERS POINT

Counseling, support and referrals for African American youth. Call: James McElroy 415/822-1585. Located at 5033 Third Street.

GCHIP

Peer counseling, support and therapy for Asian and Pacific Isander Youth. Call: Sean Nahn 415/575-3933.

REAL ALTERNATIVES PROGRAM(RAP)

Counseling and support services for Latino youth. Call:Mario Salgado or Anna Castillo 282-9884. Located at 1300 Potrero Ave, Room A3.

WORLD

A newsletter for women living with HIV and AIDS, a way to meet other women and get involved with womens issues, retreats and a speaker's bureau call or write: P.O. Box 11535 Oakland, CA 94611 510 / 658 - 6930.

My whole life has changed. I tried to shoot dope again but it just was not the same. I didn't want to die and I knew that if I continued shooting dope and disrespecting my body, I would get sick and die.

I went into a residential drug treatment program called Walden House and it totally changed every thing about ME and that old life style that I knew so well.

Today I see things differently. I seem to appreciate life more. I see things I never saw before and am able to love people and most of all, myself.

I don't know where I would be if I didn't test positive and I really don't give a fuck. The point is that I am positive and it is time to take care of my body and not let this disease get the best of me. I am writing this because I know a lot of people turn to drugs when they hurt. I am here to tell you that you don't have to do that anymore. By using drugs we weaken our immune systems and that could enable us to get sick and die. It is no fucking joke. If you have a problem with drugs or alcohol or think you might, call someone and ask for help. I did and I was able to get the help that I needed.

S.F. AIDS Hotline
1-800-FOR AIDS
AIDS/HIV Nightline
1-800-273-AIDS

MASK

Our lives in this world are very strange

People hide and refuse to change

Made-up characters in a play

Put on the show ever day

Some strive attention, others we need not mention

They are here like us, but they do not attempt to trust

We are struck by this cut, feeling entrapped like King Tut

For we realize we were them,
the ones who hide behind a face.

- D.J.B.

Where are the young women?

Hi. My name is Melissa and I am a 20 year old woman with HIV. I tested positive six months ago. I live in San Francisco, and work as an advocate for young people living with HIV. I am very involved in the HIV/AIDS community here, but I don't know any young women (ages 18-21) with HIV.

*I am feeling very lonely and really need to talk to others about what it's like to start my twenties with the worries and stresses of being HIV positive. I don't feel like a normal twenty year old who can go to college, get married, have children, work a regular job and live this typical life that I expected to. I have a hard enough time feeling comfortable dating. If you are a young woman I would love to hear from you. You can write to me c/o WORLD, P.O. Box 11535 Oakland, CA 94611. I just want to feel like I am not alone and that I really have some sort of community out there!! Thanks.**

*Reprinted with permission from WORLD P.O. Box 11535 Oakland, CA 94611, Phone: 510/658-6930

get help now

REALITY

A Newsletter By and For Youth Living with HIV

Phone Numbers Nationwide

LOUISIANA

Children's Hospital - New Orleans: Provides case management (someone who can help you find services and set up appointments), support groups for HIV+ youth. Peer education by HIV+ youth for HIV+ youth. Prevention education also provided. Call **504-524-4611.**

WASHINGTON

Youth Care - Seattle: Transitional housing (HIV+ or not) ages 18-21, call Karen Fazier. Support group for HIV+ youth 11-21, call: Shannon Davidson. For refferals, call Kristen. The number is: **206-282-1288**

NEW YORK

Adolescent AIDS Program, Montefiore Medical Center - Bronx & N.Y. City: Provides, medical and psychological care, support groups, transportation, referral's to; substance abuse, legal asst. and finacial asst., for HIV+ youth and youth ages 13-21yrs. HIV counseling and testing, risk reduction counseling and STD prevention, diagnosis/treatment. Bilingual: English/Spanish. Sliding scale fee, medicaid. For appointment call: **718-882-0023.**

MINNESOTA

Youth and AIDS Project - Minneapolis: Provides medical and psycho-social case management and referrals to HIV+ youth ages 14-21years. Also provides HIV testing, risk assessment, peer education, risk reduction counseling and follow-up to youth. Contact Kari Hillmer at **612-627-6825.**

CALIFORNIA

Children's Hospital - Los Angeles: Provides comprehensive services including case management, health care, psycho-social support, monthly activity group to youth ages 12-24 years (12-20 years, includes outpatient & inpatient services 21-24 years, outpatient services only). Confidential HIV counseling and testing is available to youth 12-20. Services are free. Contact Arlene Schneir or Lori Wolfe at **213-669-2390.**

Project AHEAD - San Francisco: Provides an HIV+ youth speaker's bureau, newsletter for youth, brochures about HIV counseling and testing. Also sponsors retreats for HIV+ youth 25 years and under. Call Ron Henderson or Antigone Hodgins at **415-753-7875.**

OREGON

Portland - Cascade AIDS Project: Provides a speakers bureau, support groups for HIV+ youth 18-25. Call Becky **503-223-5907 x113.**

Order Forms

We are happy to provide REALITY to people who can not afford to give a donation: however, we ask that anyone who can afford to donate, do so. This is free to young people.

Enclosed is my donation:_____$50-100 businesses, nonprofit

_____$20-$50 individuals _____$0-20 low income
_____additional donation to support REALITY

PLEASE MAKE CHECKS PAYABLE TO: *FRIENDS OF THE HEALTH DEPARTMENT, PROJECT AHEAD*

Name_____ **Phone**_____
Address _____
City , State, ZIP_____

Project AHEAD, Special Programs for Youth, 375 Woodside Ave., S.F, CA 94127, 415/753-7875 - Vol. 1 May 1993

NAPO Document Control Slip

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********** Correspondent Information **********

From : BRIAN MAGEE Title : CITIZEN Organization : CITIZEN
Address : 6464 Sunset, Suite 790 City : Hollywood State : CA Zip : 90028
On Behalf Of : To : KRISTINE GEBBIE

********** Subject or Title **********

Sanctuary Drug Act (SDA)

********** Keywords **********

DRUGS | INFO SERV

********** Special Instructions **********

Per Kristine, please draft a reply.

********** Assignment/Action History **********

Process Type : Direct Reply

Assignee	Initials	Action	Status	Due Date	Completed	Comments TO assignee
To Be Assigned		SDA	ASGN	10/20/93		
Ben Merrill	BM	DRAF	ASGN	10/20/93		
To Be Assigned		SDC	ASGN	10/20/93		
Sally Jones		REV	ASGN	10/20/93		
NAPO Mangement & Operations	SB	REV	ASGN	10/20/93	11/8	
Arthur J. Lawrence, Ph.D.	SB	CLER	ASGN	10/20/93	11/8	
Sally Jones		SIP	ASGN	10/20/93		
To Be Assigned		PF	ASGN	10/20/93		
To Be Assigned		SDC	ASGN	10/20/93		
Sally Jones		REV	ASGN	10/20/93		
NAPO Mangement & Operations	SB	REV	ASGN	10/20/93	11/8	
Arthur J. Lawrence, Ph.D.	SB	DIRS	ASGN	10/20/93	11/8	
Sally Jones		SFP	ASGN	10/20/93		

Related WordPerfect Filenames: _____ _____ _____

Comments FROM assignees:

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Mr. Brian M. Magee
C/O Thomas J. Magee, M.D.
6464 Sunset, Suite 790
Hollywood, California 90028

Dear Mr. Magee:

Thank you for your correspondence and that of your brother, Dr. Thomas Magee, regarding the importance of speeding up drug and therapy development for HIV/AIDS patients. You both have touched on an issue of great importance in the community and one that is getting my priority attention as the National AIDS Policy Coordinator.

We are currently exploring ways in which we can safely and effectively develop new therapeutic regimens for persons infected with HIV. Your patient illustrations and the supporting material will be of great assistance to us. The information you have provided will be considered by our staff in the development of an action plan in this area.

Thank you for all of the hard work and dedication and for supporting the President's efforts to stop AIDS.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

mailed 11/10.
Stu Lee.

November 5, 1993

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Hollywood, California 90028

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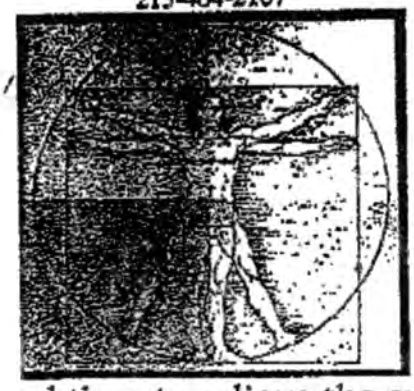
Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Prepared by:BMerrill:ONAPC:11/5/93:#7323
Revised by:SBart:ONAPC:11/8/93

Thomas J. Magee, M.D.
6464 Sunset, Suite 790
Hollywood CA. 90028
213-464-2107



Bev
draft reply

"There is no greater good than to relieve the suffering of another man"

DATE: October 12th. 1993

SEND TO: Kristine Gebbie

National AIDS Policy Coordinator

TELECOPIER NO : (202) 632-1096

COMMENTS:

We are sending 22 pages, including this cover sheet , via telecopier at 10:30 A.M./P.M. If you do not receive all of the pages or if there are any transmittal problems , please contact the undersigned at (213) 464-2107. Our FAX number is (213) 463-2882.

Office of Thomas J. Magee, M.D.

«DATA Brian:Brians letters on projects:articles/pub:clinton letter list»

July 26, 1993

«first name» «last name»
«publication name»
«address 1» «address 2»
«city», «state» «zip»

Dear «title» «last name»,

I recently came across the attached letter that was sent to President Clinton by my brother, Tom Magee, and I wanted to share it with you.

Tom is a Board Certified Internist specializing in HIV care in Southern California and wrote the letter urging the President to enact the Sanctuary Drug Act (SDA). The SDA is an idea he formulated to speed up drug and therapy development, along with information dissemination, in an effort to cure AIDS. Upon reading it, I suggested that he try to get the idea into a public forum where it may be debated, refined and executed, which is why I bring it to your attention today.

Though the idea may be seen as naive by some, I believe some version of it could be implemented by our government at a minimal cost. The benefits from the patients' and doctors' standpoint are immense. If such a program had been in effect 10 years ago, some of the current therapies (AZT/ ddi/ddc, etc.), along with the esoteric therapies (ozone, passive immune therapy, etc.) patients utilize, would not have gone beyond the Sanctuary Phase. This would have allowed other therapies to be tried and freed a lot of money up which could have back into research.

If those affected by this disease don't organize with health insurance and business organizations to send a message to our government demanding change, the memorial we build to remember AIDS victims will make the Vietnam memorial look like a postage stamp on a coffin.

Please feel free to print, reproduce, use or give this material to any party who may be interested in utilizing or publicizing the thoughts contained within it.

If you have any questions, or would like to get in touch with Tom Magee on any other AIDS related matters, please feel free to contact me at (213) 993-0433.

Sincerely,

Brian M. Magee

Encl.

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New York, NY 10020

Andrew Lippman
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Mike Royko
Tribune Media Services
64 East Concord Street
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Hunter Thompson
C/O Woody Creek Tavern
PO Box 82
Woodycreek, CO 81656

July 26, 1993

President Clinton
1600 Pennsylvania Ave.
Washington, D.C.

Mr. President,

Please find the enclosed letter that was previously sent to you. I understand that your schedule is very busy and you may not have had the time to review the letter. Due to my personal belief of its importance, I have decided to send the letter to the following publications.

- Chicago Tribune
- Chicago Sun-Times
- LA Weekly
- New York times
- Newsweek
- San Francisco Chronicle
- The Advocate
- The Village Voice
- Time
- U.S. News and World Report
- UPI
- USA Today
- Wall Street Journal
- Washington Post
- Tribune Media Services

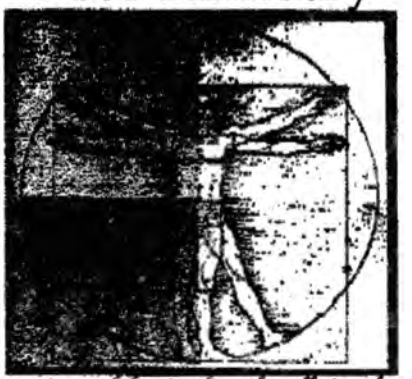
I hope to speak with you soon.

Sincerely,

Brian Magee

Sanctuary Task Force

1-800-Sanctuary



"There is no greater good than to relieve the suffering of another man"

The FDA's mission is to protect the public against harmful drug toxicities. Since the thalidomide scare of the '60's, the FDA has developed stringent guidelines and regulations for drug approval. It currently costs in excess of $190 million and takes four to ten years to bring a single drug to the marketplace. As a result of the high costs and the lengthy approval process, many potentially beneficial drugs are being tested overseas or are never seeing the light of day. In fact, some of the drugs being tested in Europe were developed at the National Institutes of Health at U.S. taxpayers' expense.

We are 13 years into the AIDS epidemic and have only three FDA-approved HIV therapies, all of which have limited benefit. Patients with late-stage, life-threatening diseases are often excluded from U.S. drug trials, and are desperate for treatment now. Physicians and their patients have been frustrated in their attempts to gain access to promising therapies, and should have access to experimental drugs. Protecting the general public against harmful side effects is necessary, but we need to adopt a different standard for life-threatening diseases. There is no side effect worse than death.

The Sanctuary Drug Act offers a solution. By establishing a Sanctuary Board comprised of prominent researchers and HIV-treating physicians as an arm of the FDA, potentially beneficial, non-FDA approved drugs warranting scientific investigation will be identified and evaluated. Those agents deemed to be within the range of acceptable risk will be selected for study inclusion. Study participants will be limited to individuals with less than one year to live. Sanctuary will supply and closely monitor the safety and efficacy of therapeutic agents in a structured, uniform study, wherein data will be collected, interpreted and disseminated to physicians via electronic data transmission. This structure will expedite our ability to recognize treatments with the potential for cure, allow alternative therapies to be scientifically evaluated, reduce exploitation by charlatans who prey upon the desperately ill with quack cures, and greatly reduce drug development costs. The expanded national access to drugs and information will also eliminate duplication of research on ineffective agents.

In dealing with the AIDS crisis, and with all incurable diseases, we must take bold and determined steps. In response to this, a group of HIV-treating physicians, AIDS activists, and HIV-infected and affected persons have recently formed the Sanctuary task force. Sanctuary will offer ***hope*** to the terminally ill -- an opportunity to improve their chances for survival and quality of life, and the opportunity to participate in the search for a cure.

For further information, please call Brian Magee at (213) 993-0433.

ΑΝΔΡΑ Δ ΩΦΕΛΕΙΝ ΑΞΙ ΩΝ ΟΙΟΙ
ΤΕ ΚΑΙ ΔΥΝΑΙΤ ΚΑΛΑΞΕΤΟΣ ΤΟΝΩΝ ..Sophocles

THOMAS J. MAGEE, M.D
6464 SUNSET SUITE 790
LOS ANGELES CA. 90028
213-464-2107

6/2/93
3:45 AM
Dear Mr. President and Mrs. Clinton:

I am writing to you at the suggestion of a friend; I am an HIV treating physician in Los Angeles plagued by the recurrent absurd situation I find my patients in and thought you might benefit from my thoughts on this situation.

The horror of HIV infection in human beings is disabling to behold. One of my more pleasant patients, Fred, was just placed in the hospital yesterday with both lower extremities swollen beyond recognition and bloody fluid dripping from wounds that open spontaneously in his flesh - this is from his Kaposi's sarcoma which was brought into his life by his HIV infection. To be sure, there are treatments, yet the best treatment-little more than fat mixed with an already approved form of chemotherapy-daunarubicin, is not available for him; but has been under clinical investigation for the last 4 years and running.[1] Who are we protecting?

A ten-year-old boy that I cared died from starvation Saturday caused by Mycobacterium Avium infection in his intestines, but he didn't just die, he died of diarrhea, chronic, unremitting, embarrassing, foul diarrhea which was brought into his life by his HIV infection.

These poignant examples are but a few of my daily frustrations and my friend suggested that I need to express my concerns over our current drug approval process as it relates to terminally ill patients, especially AIDS patients and offer a suggestion which could improve your political standing on health issues in general and most especially my patient's afflicted with AIDS. I feel, with a slight addendum to the FDA's mandate, you could accelerate the finding of a cure for this disease and others. I will try for brevity, but clearly could go on for hours.

---

[1]Lipisomal daunarubicin (LD), manufactured by Vestar in California, rumored to be approved this month? In actuality Fred could have enrolled in a randomized controlled clinical study in which he would have a 50/50 chance of receiving the drug, and when he failed to get better on the alternative treatment (AVB) he would be eligible for the trial drug (LD)-remember daunarubicin is already approved for use in humans in the US by the FDA, and lipisomal technology is nothing more than putting the drug in a fat globule, which increases the drugs half life in circulation and may facilitate its up take by tumor! I have enclosed Fred's pictures so you might have some idea as to what he is dealing with. Incidentally, he has already had the alternative treatment (AVB) and failed.

Problems concerning the drug approval process: minimizes the risk of harm, but maximizes the delay: the risk of missing potentially curative treatments.

The current drug approval process (as I understand it) is based on a wish to prevent medical mishaps as occurred with thalidomide in Europe, it is structured to insure that no medication/device used in the US will ever cause similar untoward events. This model is quite correct when it comes to wrinkle creams, cosmetic disorders and other treatments for self-limiting illnesses, as clearly these individuals are essentially healthy and can, in reality, only be harmed by the use of untested, poorly tested, or poorly understood agents used in the treatment of these conditions; hence all medications must be tested to the fullest extent possible prior to their approval/use in the United States.

Unfortunately, for critically ill individuals with less than weeks or months to live the underlying premise for drug approval is patently false. These individuals are most certainly going to die, and accordingly, the tolerance for side effects and adverse advents caused by drugs is much greater in these individuals' minds and these individuals can, in reality, only be helped by the use of untested, poorly tested, or poorly understood agents, provided there is some rational for the agents used and more importantly provided that we learn from the use of these agents. Many of my patients would suffer willingly, if there was some chance of improving their lot or even if there was some chance of advancing our knowledge - I would go further and say that several of my patients have said to me that they only wished that someone would learn from their deaths so that others might be helped. What I have learned from their deaths is an infuriating frustration at the knowledge that potentially curative agents sit on the shelves of many laboratories and pharmaceutical companies in this great country while my patients continue to die. That my patients would gladly allow themselves to be experimental subjects with little more than the expectation of death at the hands of unknown agents was initially surprising, that they would do this with only the expectation of helping someone else avoid that same agent or extend our knowledge in the treatment of HIV, is heroic and must represent the best of our human nature; unfortunately for these noble souls, little is tried, less learned. [2]

Currently two very promising agents for the treatment of HIV/AIDS are under clinical trials in Europe, both agents are made by United States companies and both companies independently have decided to go to Europe to start human trials on their compounds: GEM-91 by Hybridon Corporation and the Protease Inhibitor by Abbott Labs, Chicago IL. Why? Because of the barriers set-up by our drug approval process/tort system. By all indications both treatments look efficacious if not curative and non-toxic. The reason given by both companies for not initiating United States trials[2] was that it is easier to start clinical trials in Europe as the FDA, in essence, is demanding that the agents be proven non-toxic prior to use. Obviously, at least for the FDA, the best way to do this is to let Europe go first and observe the results, i.e., thalidomide. Unfortunately, when one thinks about it, these results and actions are clearly understandable. Any reasonable person charged with the task of drug approval in the United States with even a remote interest in keeping their job, home, bank account, reputation etc., would be out their mind to approve any new drug for use in the United

[2]Actually, trials will begin in the US sometime in the future(?) but for now these companies are awaiting FDA approval and completing additional toxicological studies asked for by the FDA.

States - what could he possible gain? I maintain a thinking individual would wait on approving any medication/device at least until it had already been approved somewhere else, the risk then being known, he would be assured no harm would come from the use of this medication/device and hence no harm would come to the approver. A thinking individual would do this for two reasons; first, those patients who would need the medication/device on moral grounds (willing to try anything, beyond hope) would by definition be the sickest and undoubtedly have little energy to fight, eventually and shortly dying; thus exerting little or no political pressure on the approver. Secondly, as he would only lose his job if an adverse effect occurred through the use of the new medication he had approved and as this is the substance of the media and the tort courts, which don't die, he would have two very good reasons to delay approval. Clearly, if you want to keep your job in the drug regulatory division, don't approve anything until it is already proven by someone else to be effective and free of side effects. Also, God help the drug company that would push to have any drug approved or used on moral grounds or try to accelerate approval prior to it being abundantly clear to the regulator that he wasn't going to lose his job by approving a thalidomide-like drug. If one considers the position of the would-be medication/device regulator a little further, one realizes that as a thinking drug regulator, being in the position to make or break any drug company by virtue of control over the approval process, he should have little to contend with from anyone interested in having a medication/device approved for sale or use in the United States; or stated differently, by vindictively delaying approval of a bothersome pharmaceutical company's new drugs one could guarantee not a peep or hint of condemnation would be heard from the drug manufacturer - the only other, directly interested, surviving party in the drug approval process.

What a dilemma, the brightest, most innovative country on the face of the planet isn't using its resources to tame the worst plague of history, is allowing agents like DDI (may substitute DDC, D4T, etc.) to languish for 5 years in clinical studies, only to finally be approved and to be found (or I can tell you, will be found) to be poorly effective, at best, in the treatment of HIV; but available to anyone who can afford the cripplingly expensive price[3] somewhat justified to offset the huge cost of complying with the clinical and toxicological data requirements by the FDA.
Might I suggest the following solution, which is potentially beneficial to my patients, U.S. pharmaceutical manufacturer, our country and you.

The Sanctuary Drug Act.
Purpose of the Sanctuary
1) To allow the free circulation of information on potentially useful agents, written by the treating physicians, on real persons with AIDS to the community at large.

---

[3]Actually if one speaks with the individuals involved in the early AZT studies, one finds that these physicians saw astonishing results in those patients started on this agent (AZT) and these same physicians pushed for rapid approval of this drug - it was, in fact, approved in a very rapid fashion; unfortunately, although AZT is very effective in the AZT naive user, or first time user, this efficacy quickly disappears in 2-6 months leaving the patient with little continuous benefit but on growing and continuous toxicity. What we are now seeing in the literature concerning the lack of effect(long term benefit) of AZT on survival in HIV infected patients, i.e., the Concord study from Europe, and the resultant class action law suits filed against Burrows Wellcome for "poisoning" patients-clearly reaffirms the dismal truth and wisdom employed by the thinking drug approvers approach. Clearly, if you want to keep your job in the drug regulatory division, don't approve anything until it is already proven by someone else to be effective and free of side effects.

a) this would discourage the continual pursuit of agents used by prior patients who died, so that patients don't keep "re-inventing the wheel" [4]

b) clearly by relying on the anecdotal model small differences of benefit or harm will be missed, but no one needs statistical methods to tell when one's t cells go up or down by a factor of 3, this change is obvious to all observers-and unfortunately this is the change we need. This sanctuary method would miss small, or in my mind with this disease, inconsequential effects, but large effects would be obvious even if only anecdotally.

c) patients will continue to seek out quack cures regardless of the laws against them as the preservation of their life would seem a higher good, even if misguided. There isn't enough man power in the nation to stop a motivated individual told that he is terminally ill from seeking out hopeful alternatives to death - why waste their experience?

As I understand the FDA to be under the control of the executive branch, and as I understand that its mission and purpose can be changed, amended or appended by executive fiat, I suggest using this power and mandating the following amendment creating to a separate division, body, committee to the Food and Drug Administration charged with the creation and maintenance of a sanctuary for the human use of currently unprovened agents/ devices. As an example: In those individuals deemed and substantiated by their physician as having less than six (6) months of life because of a life threatening, incurable disease; and having signed all necessary forms of consent and wavers of liability; and being of sound mind, such individuals shall be allowed to have their physician petition the "sanctuary" for the provision of sanctuary agents, to be used in such patients for as long as the providing physicians reports back to the sanctuary on a regular basis to be established by the sanctuary governing board, pays a nominal fee for the agent and is limited to no more than 100 patient request for any single agent in sanctuary in one year. Agents will be placed in sanctuary based on the best judgment of a group of researchers, physicians and community activist and will remain in sanctuary until it is decided that they are dangerous, ineffective or more than 50,000 request have been processed for the agent. Agents may be removed from sanctuary if no marked improvement in the patients so treated has come to light through anecdotal reporting by the treating physicians and/or as compared with the natural history of the disease itself. Drug manufacturers may submit agents to sanctuary without liability or loss of rights to the compounds and may pursue simultaneous phase one, two, and three protocols

[4] This is quite common in my experience, each new cohort infected with HIV-1 seeks out and tries the same therapies the last, dead, cohort did, e.g. , compound Q, dextran sulfate, ozone, hydrogen peroxide, intravenously hydrochloric acid, passive immunotherapy, etc.. Each desperate cohort attempts to re-invent the wheel which didn't work the first time around. Not only is the lack of efficacy disconcerting but the failure to learn from prior deaths is appalling. This lack of learning is related to two facts: most of the "practitioners of these therapies are either infected physicians themselves or 'alternative healers' and in both cases these data are not made public-the treatments being illegal or the treating physician dying from HIV and with him any information concerning the treatment efficacy or rather obvious lack thereof. During my treating of HIV infected patients I have seen this cycle repeat itself 3 times and I see no end in sight. It has two distressing side effects, one, more effective or even different therapies are not sought out and, two, the burden or proof is placed on the physicians who don't believe these therapies effective. Patients have said to me: "if it can't hurt me don't you think I should do it" or "doesn't it make sense, if ozone, bleach, hydrochloric acid, etc. kills the virus in cell culture won't it kill the virus in my blood" or " I have a friend whose T cells went up 400 by using rectal enemas of bitter melon extracts". How does a physician answer these questions? Scientifically? With what data? In this situation perhaps one can answer an anecdote with another anecdote or several thousand of them. For example, if every one of the individuals who comes to me expressing a desire to do intravenous compound Q could be referred to the Sanctuary data base of 5000 experiences with this agent and if 90% of the patients had died, got worse, did nothing, etc. I would suggest that these same patients initially determined to undertake such therapy would start looking for another treatment modality.

as currently recognized by the FDA. The sanctuary will be charged with adding and removing medications/devices from sanctuary status, maintenance and dissemination of a timely account based on the feed back from physicians using the sanctuary drugs and in allowing or disallowing physician participation in the sanctuary program based on the sanctuary's reporting requirements. Further the Sanctuary will maintain an acceptable standard of toxicity and ensure such data is present and available on all agents in sanctuary prior to release of compounds from sanctuary to the treating physician, this requirement for limited toxicity shall be judged in, rat, rabbit and dog but no requirement on human toxicology will be required on sanctuary agents prior to their release with all parties being warned as to the limits of the toxicological data. Sanctuary will transmit all toxicological summary data to requesting physicians with the sanctuary drugs. The sanctuary will use the funds it collects from the fee charged for providing agents to physicians/patients to pursue the study of the toxicology on agents decided by the committee for use in the sanctuary but not having drug company sponsorship or prior toxicological data, an example being a natural compound or chemical compound having promise is cell culture studies but not attractive to drug manufacturers for reason of profit, patent etc.

This act would sub-serve several functions:
1) Any agent having tremendous curative power, even if non-patentable or widely available would be immediately obvious to those individuals both in and out of the sanctuary who are familiar with the disease process and would hopefully, having shown such promise in sanctuary, be pursued further in more formal clinical trials.
2) All or most covert use of agents in terminal disease would become public as the sanctuary would have these agents and proponents, or more importantly their patients, could look at the results, or read the anecdotal reports from many physicians who had direct experience with the agent prior to trying it themselves. This would help to limit the wildly successful, unsubstantiatable claims made for coffee enemas, or some other less absurd treatment done currently only in one place in Mexico, etc. and not capable of being refuted or even analyzed as no reasonable individual would risk losing their license doing something they had no faith in; nevertheless, some more evenly tempered individuals might, at the patients request provide such therapy if available in sanctuary and would by definition report back to sanctuary, thus normalizing the reality of the agent and its effect in a broad group of patients and in a broad range of doctor's hands
By not allowing any one group to dominate the anecdotes or spread nonsense amongst desperate patients, the only motivation served by the sanctuary act, and in the requesting of a sanctuary agents, would be for ones patient's health and survival, the patient having failed all else.
3) This act would provide a restraint on those unscrupulous charlatans who practice beyond and within our borders and drain our citizens/patients of resources, as any physician who cares for the terminally ill can attest, this is very difficult to prevent. By virtue of a sanctuary act a physician could use the same or similar agent available out of the sanctuary drug and the reports of thousands of such US physicians, all using the same pure agent, could be read by potential sanctuary users and patients and physicians prior to embarking on the use of such an agent. Patients would then have many reports to review rather than the one report of cure from one individual with one treatment available only in Mexico, Africa, etc.

4) The great cost of drug development could be brought to a fraction of its current cost as "home-run" agents would be evident and their major toxicities also evident. Small firms with little capital could submit or publish their data as is currently done and sanctuary committee could select their agent for placement in the sanctuary
5) Agents in the sanctuary would be provided by drug manufacturers at no cost and would be pure, the manufacturer obtaining very rapid data on the agents effect in humans in return for provision of the agent and the toxicological animal data.
6) The sanctuary allows for a rapid evaluation of many agents with potential for cure, as contrasted with the 9 billion dollars we have spent comparing AZT to DDI. through the ACTG's
7) Patients and physicians stop re-inventing the wheel[5].

Benefit to United States patients:
1) Untold thousands of patients now go to Mexico, Europe etc. to seek out "cures" at great expense and untold grief. Given the availability of the same agents through their doctors these same patients (having failed all conventional therapy and with less than 6 months to live) would surely prefer to stay at home and some data could be collected on these agents at the same time.
2) The sanctuary agent might just work. Agents which clearly already work in the test tube could be used in humans in a matter of months rather than years.

Benefit to the United States pharmaceutical manufacturer:
In essence the companies could choose to place a drug in sanctuary and obtain information on its human toxicity and efficacy without spending the 10 million it currently costs to bring an agent through clinical trials. Having such advanced warning on agents under consideration by the drug companies for development is invaluable and for those agents which showed promise in sanctuary efforts could be made to accelerate, through the normal channels of phase one, two, and three, the wider availability of the agent to less ill patients who would not meet the definition of sanctuary users.

Benefit to you:
Clearly more previously healthy young Americans have died from HIV (200K) than have died in W.W.II, Korea and Vetnam. Recognized or not, this is a state of emergency. Each individual who dies of AIDS has on the average 30 years of training spent on him and these same individuals were expected by society to perform for another 30-40 years--what an incredible waste of productive man years. Thirty years times 200K men equals 6 million man years of production!. These are the individuals who were to pay taxes and take care of society-but now just draw on society and die.
All of those persons infected with HIV dead or alive have families that are extremely anxious that something be done and would be extremely grateful to anyone accelerating the process of finding a cure. This addendum to the FDA costs nothing, wins popular support

[5]One of the truism of medicine is that when a treatment for a disease works, for example the treatment of testicular cancer with 98% cure, there is very little charlatan activity, or alternative medicine in these diseases, however, when current therapy is ineffective there is a burgeoning market in quack cures. Much of the problem with HIV is that we have no effective cure. When one is found, most of the problems surrounding the disease treatment with bizarre agents disappears.

and could dramatically accelerate the discovery of cure. I can think of no greater act that could be done to win popular support for your administration than to allow the terminally ill to go first and experiment with their and their families' consent and the approval of their physicians in a situation so desperate for cure.

THOMAS J. MAGEE, M.D.[6]

[6]The letterhead pictures Oedipus contemplating the riddle of the sphinx to save the city of Thebes from a plague. Few would attempt this method of solving their problems, for in order to receive the solution to your problem you would first have to answer the riddle posed by the sphinx, if the riddle was answered correctly the sphinx would tell you how to overcome your problem, if the riddle was answered wrongly, the sphinx would leap from its pedestal grab the questioner by the neck and cast him into the abyss. Oedipus solved the riddle of the sphinx and saved the city of Thebes from the plague. The writing under the picture is attributed to Oedipus and translated from Greek states "there is no greater good that to relieve the suffering of another man."

EXPANDED SANCTUARY DRUG ACT OUTLINE

I. PATIENT QUALIFICATIONS
- A. Life-threatening, incurable illness
- B. Expected to have less than 6 months to live
  - 1. As determined by actuarial tables
  - 2. Certified by treating/requesting physician
- C. Mentally competent - see Section I/B/2
- D. Informed consent , liability waivers
  - 1. Discussion between patient and treating physician detailing all risks and unknowns, Sanctuary function, rules for both patient and physician
  - 2. Patient agrees to hold harmless all parties involved in the production, administration, distribution, and involvement in the Sanctuary
  - 3. Discussion and patient's agreement are video taped, and consent and liability forms are signed by patient

II. SANCTUARY BOARD MEMBER QUALIFICATIONS
- A. Has been a primary care physician for 500+ HIV patients or practice has been devoted to HIV primary care for two or more years
- B. Agrees to report to Sanctuary board on a regular basis on patient status in a format designed by Sanctuary board
  - 1. Monthly meetings of participating physicians via teleconference or ISDN video phone. Equipment will be provided by the Sanctuary and remain the property of the Sanctuary.
  - 2. All meetings will be recorded and made available to the public.
- C. Physicians will not receive any compensation for serving on the Sanctuary, but will be indemnified against tort actions by the State.
- D. Physicians will be limited as to the number of patients allowed into the Sanctuary annually.
- E. Will provide Sanctuary agents to Sanctuary patients at cost.
- F. Physicians' charges to Sanctuary patients for other services will be at the physician's discretion.
- G. Term of membership to be two years
  - 1. Year One of Sanctuary - 10 member physicians
  - 2. Year Two of Sanctuary - 20 member physicians
- H. Appointment to Sanctuary membership by Sanctuary board/*governor/president.*

III. SANCTUARY BOARD AND STAFF
- A. Board appointed by governor/president
- B. Staff (minimal) hired by Board to manage data

C. Responsibilities of Board
1. Monitor Sanctuary physician compliance
2. Selection of agents for addition to Sanctuary
3. Review Sanctuary physician reports of toxicology/efficacy of Sanctuary agents
4. Contract with a cell culture lab (NIH, university) for initial toxicological studies on untested agents
5. Act as liaison with pharmaceutical companies to insure cooperation with Sanctuary agenda
6. Manage funds generated by Sanctuary agent fees and government funding or donations
7. Prepare and make available to the public results of Sanctuary agents, good or bad.
8. Establish the parameters of Sanctuary dissolution
9. Choose physicians, patients, and agents for participation in Sanctuary

D. Will receive no compensation for serving on the board, but will be indemnified against tort actions by the State

IV. PHARMACEUTICAL COMPANIES
A. May submit agents to Sanctuary without liability or loss of rights to compounds
B. May simultaneously pursue phase one, two or three protocols as recognized by the FDA.

V. SANCTUARY AGENTS
A. Agent becomes known to Sanctuary board through
1. Reading
2. Anecdotal experience

B. Agent under consideration is subjected to the following qualifying questions:
1. Is the agent currently available to physicians via the compassionate use program? If so, exclude the agent from further consideration.
2. Is the agent available in another country? (The patient can obtain the agent through a prescription.) If so, exclude the agent from further consideration.
3. Is there evidence of effect against HIV in non-tumor human cell culture systems (e.g., PBMC's)? If there is no evidence of effect, the agent is excluded until data showing effect become available. Developing such data may be a function of the Sanctuary.
4. Is the therapeutic to toxic ratio in human non-tumor cell culture less than 2^1? If so, the agent is excluded from further consideration. (Note: All agents are toxic if given in large enough amounts. Digoxin, with a therapeutic to toxic ratio of approximately 2^1, is the currently accepted treatment for congestive heart failure, which has an average survival of around six months to one year. A therapeutic to toxic ratio of 2^1 means that twice the treatment dose can kill you.)

C. The agent is subjected to the following questions in order to accelerate placement in the Sanctuary:

1. Has the agent ever been or is it currently being used in humans for another purpose? In either case, toxicity is known and the agent may go directly to Sanctuary unless it has been excluded in Section V/B.

2. Testing

a. Assuming no animal toxicity is found, and the agent has never been used in humans for any purpose, the agent being considered for Sanctuary status must have at minimum the LD_{50} status (the dosage necessary to kill 50% of the test animals) in mice prior to being placed in Sanctuary. If no LD_{50} exists (some medications are so harmless, you can't really kill a test animal with any reasonable amount of the agent), then the agent must be shown to be tolerated at a dose at least 30 times greater than that expected to be used in humans as estimated on a mg/kg dosing schedule, and as derived from cell culture calculations using a volume of distribution of total body water (for example, let us say that 1 microgram/ml of compound Y is shown to kill all HIV infected cells in cell culture, has no cell culture toxicity on healthy cells up to 2 times this dose, and further, no LD_{50} could be found in mice at doses 30 times greater that estimated to be used in humans on a mg per Kg basis. Then the mice should tolerate .6 x the body mass in Kg= total body water in liters. [total body water in mls] x [1 microgram/ml] x 30 = the dose needed to be tolerated by the mouse.).

b. Animals will be maintained for one month post-exposure to assess more long-term pathological effects, and will be studied via necropsy to look for organ damage prior to placement of the agent into Sanctuary. If organ damage is found, the compound is excluded.

3. Once the agent of interest has cleared the prior hurdles, it will be placed in Sanctuary

a. Initially, the drug will be released to ten physicians for use by ten patients, for one month.

b. The drug will be placed on provisional status for an additional month while data on original patients is being reviewed.

c. At this point, the Board will either approve continued use, or remove the agent from Sanctuary if an obvious pattern of toxicity is apparent.

d. If the Board approves continued use, the agent will be open to the next 100 requests.

e. When another 100 patients have received the drug for one month (or at any time prior if the Board so decides), the drug will again be placed on provisional status for a month while the data a reviewed.

f. If no pattern of toxicity has emerged, the agent will be made available to the next 1000 candidates (total patients exposed - 1110).

g. At this point, the agent is closed to further use by anyone through the Sanctuary unless the Board

votes to extend or enlarge the pool of patients receiving the agent.

h. In any case, with each order of magnitude increase in patients taking or having taken the drug, a one month time-out will be observed to allow for collection and analysis of data, provided by the treating physician.

D. Problems

1. Paying for all this
   a. Administration
   b. Animal toxicology
   c. Cell culture
   d. Data base
   e. Public access
2. Sources
   a. Public funds
   b. Donations
   c. Agents will be provided to any licensed physician in the U.S. for a monthly user fee of *$100* per patient
3. The one patient for whom the agent was a Godsend
   a. Any patient/physician user of the Sanctuary who decides to continue to take the agent of study after having been on the agent for more than four months (this being the usual termination point if no effect or toxicity is seen) will be allowed to continue to receive the agent at their discretion, provided they continue to report to the Sanctuary on the patient's condition monthly, and continue to pay the user fee.
   b. This grace period will continue for up to six months after the agent has been removed from the Sanctuary for reasons of non-efficacy, but not for reasons of toxicity.
   c. If no drug company has decided to pursue the agent for commercial use, and if the Sanctuary has not continued to expand access, or the Sanctuary has dropped the agent from further consideration, the agent will no longer be provided through the Sanctuary.
   d. If toxicity was the reason for removal from the Sanctuary, then that agent will not be made available to anyone from that point onward.

OUTLINE FOR PROPOSED SANCTUARY DRUG ACT

I. PATIENT QUALIFICATIONS
- A. Life-threatening, incurable disease
- B. Expected to have less than six months to live
- C. Informed consent waivers, liability waivers
- D. Mentally competent
- E. Physician's verification of A through D

II. PHYSICIAN REQUIREMENTS
- A. Agrees to report to Sanctuary board on regular basis on patient status
- B. Pays nominal fee for Sanctuary drugs
- C. Limited to 100 patients/Sanctuary drug/year
- D. Provide Sanctuary drugs to patients at cost

III. SANCTUARY DRUG/AGENT REQUIREMENTS
- A. Meets Sanctuary toxicity standards based on animal studies
- B. Are not deemed dangerous or ineffective by the Sanctuary board
- C. Are supplied to the Sanctuary at no cost by manufacturers
- D. Removal from Sanctuary
  1. No marked improvement in patients, as compared with the natural progression of the disease, has been reported by physicians
  2. Shown to be dangerous
  3. More than 50,000 requests have been received by Sanctuary

IV. SANCTUARY BOARD
- A. Researchers, physicians, community activists
- B. Maintain an acceptable standard of toxicity
- C. Add to and remove from the Sanctuary medications/devices
- D. Maintenance and dissemination of anecdotal results from participating physicians
- E. Allowing/disallowing physician participation in program based on physicians' compliance with reporting requirements
- F. Transmit toxicological summary data to physicians
- G. Use funds collected from participating physicians to pursue the study of the toxicology of agents chosen by the committee for inclusion in Sanctuary that do not have drug company sponsorship or prior toxicological data (i.e., natural compounds or compounds showing promise in cell culture studies, but unattractive to drug companies for patent or profit reasons)

V. DRUG MANUFACTURERS
- A. May submit agents to Sanctuary without liability or loss of rights to compounds
- B. May simultaneously pursue phase one, two, or three protocols as recognized by the FDA

VI. BENEFITS
- A. Speed in recognizing agents with great potential for cure
- B. Agents without great profit potential would be evaluated/utilized
- C. Alternative therapies scientifically evaluated
- D. Drug development costs could be greatly reduced
- E. Purity and dosageof agents would be standardized, assuring:
  1. Patient safety
  2. A level playing field for comparison of agents
- F. Charlatanism reduced
- G. Tens of thousands of productive lives might be salvaged

THE PROCESS BY WHICH AN AGENT IS PLACED INTO THE SANCTUARY, IS MADE AVAILABLE, AND IS TAKEN OUT OF SANCTUARY

Membership to Sanctuary:

Anyone may be admitted to Sanctuary committee status provided that they have treated more than 500 HIV patients during their career as a primary caring physician.

Sanctuary shall have 10 members the first year and 20 members the second year; their terms will be for two years. This group will be appointed by the governor of the state or president of the US.

Meetings will be held on a monthly basis via satellite up link, down link, or ISDN interactive video phones. All meetings will be recorded and available to the public. The equipment will be provided by the Sanctuary to its members while the physician is a member of the Sanctuary, and will be transferred to new physicians at the end of their tenure.

Physicians will not receive any compensation for serving on the Sanctuary, but will be indemnified against tort actions by the state or federal government.

1) Discovery

a) An agent becomes known to the members of the Sanctuary through:

1) Reading
2) Anecdotal experience

b) The agent is subjected to the following questions in an attempt to eliminate it from placement in the Sanctuary:

1) Is the agent currently available to physicians via the compassionate use program? If so, exclude the agent from further consideration.

2) Is the agent available in a foreign country? Through use of a prescription the patient can obtain this already. If so, exclude the agent from further consideration.

3) Is there evidence of effect against HIV in non-tumor human cell culture systems, e.g., PBMC's? If no effect in this system, the agent is excluded from further consideration until such data become available. May be a task of the Sanctuary division.

4) Is the toxic to therapeutic ratio in human non-tumor cell culture less than 2[1]? If so, the agent is excluded from Sanctuary.

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[1] All agents are toxic if given in large enough amounts, e.g., water. We currently accept the use of Digoxin in our treatment of congestive heart failure and the therapeutic to toxic ration is approximately 2, that is, twice the

c) The agent is subjected to the following questions in order to accelerate placement in the Sanctuary:

1) Has the agent every been used in humans, albeit for another purpose, or is the agent currently used in humans for another purpose? In either case the toxicity in humans is known. If so, it may go to Sanctuary directly[2], provided it has not been excluded in Section b.

2) Testing

a) Assuming no animal toxicity is known, and the agent has never been used in humans for any purpose, the agent being nominated for Sanctuary status must have at minimum the LD-50[3] status in the mouse prior to being placed into Sanctuary, and if no LD-50 exists[4], then the agent must be shown to be tolerated at a dose of at least 30 times that expected to be used in humans as estimated on a mg/kg dosing schedule, and as derived from cell culture calculations using a volume of distribution of total body water.[5]

b) Animals will be maintained for 1 month post exposure to assess for more long term pathologic effects, and will be studied via necropsy to look for organ damage prior to placement of the agent into Sanctuary. If organ damage is found, the compound is excluded.

3) Provisional release

a) Prior to receiving any medication or agent from the Sanctuary a video-taped discussion between the treating physician and the treated patient will be recorded in which all the risk and the unknowns are discussed and the patient agrees to hold harmless all parties involved in the production, administration, distribution and involvement in the Sanctuary.

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treatment dose of this medication can kill you. Congestive heart failure has a very poor natural history with the average survival being somewhere around 6 months to 1 year.

[2] I am thinking of one of the early syphilis drugs which was found to have anti-HIV activity, but is no longer made as it has been superseded by better agents for the treatment of syphilis; nevertheless, it was previously used in humans and its toxicities could be gleaned from the literature of the time.

[3] LD-50 refers to the dose of drug necessary to kill 50% of the animals.

[4] Some medications are so harmless that you really can't kill the test animal with any reasonable amount o the agent.

[5] For example, let us say that 1 microgram/ml of compound Y is shown to kill all HIV infected cells in cell culture having no cell culture toxicity on healthy cells up to 2 times this dose, and further, no LD 50 could be found in mice at doses 30 times greater that estimated to be use in humans on a mg per Kg basis. Then the mice should tolerate .6 x the body mass in Kg= total body water in liters. (Total body water in mls) x (1 microgram/ml) x 30 = the dose needed to be tolerated by the mouse.

b) All patients who petition the Sanctuary for agents must have less than 6 months to live as determined by current actuarial tables on HIV as determined by the CDC, and further supported by a statement from their treating/requesting physician.

c) Assuming that the agent of interest has cleared the prior hurdles, it will be placed in Sanctuary. The drug will be released to 10 treating physicians for ten patients initially, and then held in a provisional status for one month during which the drug will not be released until data from the initial 10 patients has been reviewed by the committee. The committee will have two choices, either to approve continued use or to remove the agent from the Sanctuary. If an obvious pattern of toxicity is present in the eyes of the committee, the agent will be removed from the Sanctuary. If no pattern of toxicity exists, in the eyes of the committee, then the agent of interest will be open to the next 100 requests. When another 100 patients receive the agent, or at any time prior if the committee so decides, the agent is again placed in provisional status and distribution is held for another month. At the end of the month the data will be reviewed again by the committee, and if no pattern of toxicity exists, the agent will be open to1000 more candidates (total patients exposed =1110), and then closed to further use by anyone through Sanctuary unless the committee votes to extend or enlarge the pool of patients receiving the agent. In any case, with each "order of magnitude"[6] increase in patients taking or having taken the drug, a one month time-out will be observed to allow for the collection and analysis of data, provided by the treating physician.

d) The problem of paying for the Sanctuary and the cost of running animal toxicology, making and shipping drugs, and maintaining a public access bulletin board "data base." Agents will be provided to any licensed physician in the US, provided that a user cost of 100 dollars has been paid for each months worth of agent received.

e) The problem of "The one patient for whom the agent was a God send." Any patient/physician user of the Sanctuary who decides to continue to take the agent of study after having been on the agent for more than 4 months (this being the usual termination point if no effect or toxicity is seen), will be allowed to continue to receive the agent at their discretion provided they continue to report to the Sanctuary on the patient's condition monthly and continue to pay the user fee. This grace period shall continue for up to six months after the agent has been removed from the Sanctuary for reasons of non-efficacy, but not for reasons of toxicity. Thereafter if no drug company has decided to pursue the agent for commercial use and if the Sanctuary as not continued to expand access and/or the Sanctuary has dropped the agent from further consideration, the agent will no longer be provided through the Sanctuary. If toxicity was the reason for removal from the Sanctuary, then no agent will be made available to anyone from that point forward.

---

[6] An order of magnitude is a factor of 10, so the number 1000 differs from the number 1 by 3 orders of magnitude

Dear Doctor (or Colleague),

As a fellow physician treating HIV/AIDS patients, I'm sure you have become as frustrated at the inability to gain access to therapies for our desperately (or terminally) ill patients as I have. I've recently come upon an idea that addresses this situation and would like your feedback on it.

The Sanctuary Drug Act would establish a vehicle to supply and monitor the efficacy of non-FDA approved drugs for the terminally ill. Sanctuary proposes that those with 6-12 months to live be allowed to try untested drugs in a structured study, where data is collected from and disseminated to participating physicians. This structure would speed up our ability to recognize agents with a great potential for cure, allow alternative therapies to be scientifically evaluated, eliminate the charlatans who prey upon the desperately ill, and greatly reduce drug development costs. Perhaps as importantly, many terminally ill persons who feel they have nothing to lose would welcome the opportunity to make the end of their lives more meaningful by advancing knowledge in this area while giving hope for a cure to others.

Thank you for your hard work and compassion.

Please indicate your endorsement of this concept below.

Sincerely,

Thomas J. Magee, MD

Please take a minute to FAX back your interest in this concept to The Sanctuary Act Foundation.

☐ Yes I would support the Sanctuary Act.

☐ Yes I would support the Sanctuary Act and would like to participate in studies for my patients.

☐ Please send me more information to:_____

_____

I endorse the idea of the Sanctuary Drug Act and authorize the Sanctuary Task Force to use my endorsement in their efforts to promote the creation of the Sanctuary. I understand that my endorsement implies no obligation on my part, but is simply a reflection of my support of the Sanctuary Drug concept.

NAME _____ DATE _____

Please return to the Sanctuary Task Force at:

Sanctuary Task Force
c/o Knowing, Inc.
6565 Sunset Blvd., Suite 416
Hollywood, CA 90028

or FAX (213) 993-0430

November 5, 1993

Kristine Gebbie, RN, MN
National AIDS Policy Coordinator
The White House
Washington, D.C.

Dear Ms. Gebbie:

Thank you for your personal response to my fax letter. My apology for not getting your title correct. I am hoping that your statement of "the show is on the road" will prove fruitful for all those who are HIV positive or are in a stage or ARC or AIDS. Twelve years has gone by with very little to show for such a long time span. It is amazing to me how the research establishment cannot outwit a retrovirus. Hopefully with you as coordinator, the research effort will become a bit more imaginative.

Again thank you for responding. One often wonders if there is anyone at the other end of a fax letter. Certainly in this case there was. Good luck in your efforts to bring some semblance of control over a long neglected area of medical research.

Gerald J. DeGregori

Gerald J. DeGregori
35 French Creek Place
San Mateo, Ca. 94402-4009
(415) 341-8139

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Steven M. Hensel, Chair
Design Industries Foundation for AIDS
2202 North Pacific Avenue
Seattle, WA 98103

Dear Steven:

I am pleased to learn that there is a DIFFA chapter in Seattle. Nationally, DIFFA is an exemplary foundation that leads the way to help those affected by HIV and AIDS. With 16 million dollars granted throughout the country to date, DIFFA has emerged at the forefront in the fight against AIDS.

In Seattle, a DIFFA chapter has the potential to make a tremendous contribution towards ending this epidemic. By combinng the attributes of this national affiliation with the caring spirit of the Pacific Northwest's people, you have the unique opportunity to bring education, hope, and financial aid to where it is most needed.

I wish that every city was blessed with the committed core of volunteers as evidenced in DIFFA/Greater Seattle. I encourage your entire community to support your important mission -- I do.

Sincerely,

Kristine M. Gebbie
National AIDS Policy Coordinator

NATIONAL AIDS POLICY OFFICE
OFFICE OF THE COORDINATOR

ROUTING SLIP

DATE: 1/3

TO: KG.

FROM: ✓ W. STEVE LEE

____ For your information

✓ For your action review/signature

____ Review and comment by (date) ____

____ Prepare reply for Coordinator's signature

____ Reply directly and blind copy Coordinator

____ **Circulate/**forward to: ____

____ File

COMMENTS: This was sent to you as
if it were promised. DIFFA does
good work. They want to use
the letter to get support — \$
volunteers, etc.

SB

DIFFA / GREATER SEATTLE

Design Industries Foundation for AIDS

Dear Kristine Gebbie,

It was a pleasure to hear you speak in Dallas last month and to talk with you today. Thank you so much for taking the time to send a letter to help us establish ourselves as a viable chapter.

Perhaps the letter could read something like this....

Dear Steven Hensel,

I am pleased to learn that there exists a productive DIFFA chapter in Seattle.

Nationally DIFFA is an exemplary foundation leading the way to help those affected by HIV and AIDS. With over 16 million dollars granted throughout the country today, DIFFA has emerged at the forefront in the fight against AIDS.

For Seattle specifically a DIFFA chapter has the potential to contribute significantly to the cause. By combining the attributes of this national affiliation with the caring spirit of the Pacific Northwest's people you have a unique opportunity to bring education, hope and financial aid to where it is most needed.

I wish that every city were blessed with the committed core of volunteers as evidenced in DIFFA/Greater Seattle. I encourage your entire community to support your important mission.

Sincerely.....

Please feel free to edit to suit your taste. Again, thank you very much for helping us to help the men, women and children affected by AIDS and the HIV virus.

Sincerely,

Steven M. Hensel
Chair

2202 North Pacific – Seattle, Washington 98103
Telephone: 1-206-633-2265 Facsimile: 206-633-2346

545776

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Michele A. Zavos
AIDS Coordinating Committee
American Bar Association
1800 M Street N.W.
Washington, DC 20036

Dear Ms. Zavos:

Thank you for the copies of the Issues Relating to AIDS and Health Care Reform from the American Bar Association. They will prove useful as my staff and I continue to monitor the health proposals from an HIV/AIDS perspective. Please stay in touch as the debate moves through Congress.

Sincerely,

Kristine M. Gebbie
National AIDS Policy Coordinator

AMERICAN BAR ASSOCIATION **AIDS Coordinating Committee**
1800 M Street, N.W.
Washington, DC 20036
(202) 331-2248
ABA/net: ABA339
FAX: (202) 331-2220

Kristine Gebbe
Coordinator
National AIDS Policy Coordination Office
200 Independence Avenue, SW
Washington, DC 20201

OCT 27 1993

Dear Ms. Gebbe:

I am pleased to enclose for your review five review copies of Issues Relating to AIDS and Health Care Reform produced by the American Bar Association's AIDS Coordinating Committee as part of the ABA's overall submission to the President's Task Force on Health Care Reform. Although the ABA does not have specific policy in the area of AIDS and health care reform, this report represents the views of the ABA's AIDS Coordinating Committee, which is charged with developing policy recommendations for the ABA as a whole. I hope the report will prove useful to you in your work on health care reform and AIDS-related issues.

In addition, please find enclosed a brochure describing the work of the AIDS Coordination Project and the Coordinating Committee.

Sincerely,

Michele A. Zavos

Enclosure

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Jenny Jones, M.S.W.
Coordinator, Family Support Services
Los Angeles Pediatric AIDS Network
c/o Childrens Hospital Los Angeles
4650 Sunset Boulevard, Box 30
Los Angeles, CA 90027

Dear Ms. Jones:

Thank you for participating in the meeting in Los Angeles on Tuesday evening, October 26. I appreciate the opportunity to meet some of those working on HIV/AIDS issues in Los Angeles. Please stay in touch as issues, concerns or opportunities arise.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Zoe-Anne Fitzhugh, RN, MS
HIV Clinical Nurse Specialist
Internal Medicine Nursing
Room 6900, LAC + USC Medical Center
1200 No. State Street
Los Angeles, CA 90033

Dear Ms. Fitzhugh:

Thank you for participating in the meeting in Los Angeles on Tuesday evening, October 26. I appreciate the opportunity to meet some of those working on HIV/AIDS issues in Los Angeles. Please stay in touch as issues, concerns or opportunities arise.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Mr. Elliot Johnson
Administrator, AIDS Related Services
Los Angeles County and University of Southern
California Medical Center
1175 N. Cummings Street
Los Angeles, CA 90033

Dear Mr. Johnson:

Thank you for participating in the meeting in Los Angeles on Tuesday evening, October 26. I appreciate the opportunity to meet some of those working on HIV/AIDS issues in Los Angeles. Please stay in touch as issues, concerns or opportunities arise.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 5,1993

Mr. Stewart Sokol
Director HIV/AIDS Services
South Bay Free Clinic
710 Pier Avenue
Hermosa Beach, CA 90254-3885

Dear Mr. Sokol:

Thank you for participating in the meeting in Los Angeles on Tuesday evening, October 26. I appreciate the opportunity to meet some of those working on HIV/AIDS issues in Los Angeles. Please stay in touch as issues, concerns or opportunities arise.

Sincerely,

Kristine Gebbie

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Mr. Dean M. Goishi
Director
Asian Pacific AIDS Intervention Team
1313 West 8th Street
Suite 224
Los Angeles, CA 90017

Dear Mr. Goishi:

Thank you for participating in the meeting in Los Angeles on Tuesday evening, October 26. I appreciate the opportunity to meet some of those working on HIV/AIDS issues in Los Angeles. Please stay in touch as issues, concerns or opportunities arise.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 5,1993

Ms. Dana Gorbea-Leon
Executive Director
People with HIV/AIDS Action Coalition
3626 Sunset Boulevard
Los Angeles, CA 90026

Dear Ms. Gorbea-Leon:

Thank you for participating in the meeting in Los Angeles on Tuesday evening, October 26. I appreciate the opportunity to meet some of those working on HIV/AIDS issues in Los Angeles. Please stay in touch as issues, concerns or opportunities arise.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Mr. Ricardo A. Contreras
Lead Health Promoter
Clinica Msr. Oscar A. Romero
2675 West Olympic Boulevard
Los Angeles, CA 90006

Dear Mr. Contreras:

Thank you for participating in the meeting in Los Angeles on Tuesday evening, October 26. I appreciate the opportunity to meet some of those working on HIV/AIDS issues in Los Angeles. Please stay in touch as issues, concerns or opportunities arise.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Kenneth I. Shine, President
Institute of Medicine
National Academy of Sciences
2101 Constitution Avenue
Washington, DC 20418

Dear Ken:

Thank you for your the invitation to serve on the Institute of Medicine's Roundtable for the Development of Drugs and Vaccines Against AIDS. Yes, I'll be happy to participate. In fact, I have already confirmed my participation in the November 29 meeting.

I look forward to continued work.

Sincerely,

Kristine M. Gebbie
National AIDS Policy Coordinator

OCT 27 1993

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE WASHINGTON, D. C. 20418

KENNETH I. SHINE, M. D.
PRESIDENT

Steve
prepare "yes, I do
welcome to
participate"
letter

October 22, 1993

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator
Executive Office of the President
750 17th St., NW, Suite 1060
Washington, D.C. 20503

Dear Kristine:

This letter extends to you a formal invitation to serve on the Institute of Medicine's Roundtable for the Development of Drugs and Vaccines Against AIDS. Your appointment will commence immediately and continue through December 31, 1993; however, we anticipate that the Roundtable will be renewed for another two-to-three year term.

The Roundtable promotes the expeditious development of drugs and vaccines against HIV infection and AIDS. It serves as a mechanism to foster effective communication among representatives from the federal government, academia, the pharmaceutical industry, and patient advocacy groups, and holds workshops, symposia, and conferences to explore topics it identifies as important. The Roundtable meets approximately three to four times each year. As you know, the Roundtable's next workshop, *Towards an Understanding of the Correlates of Protective Immunity to HIV Infection,* will be on December 10, 1993, preceded by a dinner/executive session on December 9. You will receive further details about this meeting from project staff.

The Roundtable's work will greatly benefit from your participation, and it is my sincere hope that you will accept this invitation to serve. Our activities are dependent on the voluntary services that are provided by our members and other experts in the field under study. I would appreciate an early written reply. If you have any questions about the project, please call Leslie Hardy, Study Director for the Roundtable, at (202) 334-2453.

Please accept my appreciation for your willingness to devote time and attention to accomplishing this important task.

Sincerely,

Kenneth I. Shine, M.D.
President

cc: Leslie Hardy

THE WHITE HOUSE

WASHINGTON

November 5, 1993

Charlotte Lang
3180 N.W. Division #219
Gresham, OR 97030

Dear Charlotte:

Thank you for letter requesting educational materials on HIV and AIDS to support your upcoming speech. I have asked the National AIDS Clearinghouse to rush some materials to you. Hopefully, they will arrive about the same time as this letter.

If, for some reason, they do not, please call me at (202) 632-1090 and I can follow-up.

Good luck with your speech.

Sincerely,

W. Steve Lee
Executive Assistant to
National AIDS Policy Coordinator

Please ask
Hotline to rush packet
Of govt info to her —

& send note that we
have placed that
request —

Thanks —

~~Jacqueline Geeley~~.
Jacqueline Geeles - NACH.
~~[illegible]~~
~~St Dept [illegible]~~.

10/26/93

Kristine Gebbie
2737 Devonshire Place NW
#315
Washington D.C. 20008

Dear Kristine!

I am writing to follow-up on our brief conversation last Sunday at St Luke Church. I am glad I had the opportunity to hear you speak. Your analogies about light & dark & how our christian beliefs have changed over time were enlightening. Your speech affected many of us in a positive way. And I know a woman in the pew behind me even said she was going to ask for copies of your speech to distribute to another group. Thank you for sharing your Christian beliefs with us. It took courage to stand infront of the whole congregation & Pastors Myrin & David to tell us something we didn't want to hear & with which we may even disagree. I wish my mother could have heard you speak, but unfortunately for me, she lives in North Dakota.

You indicated in our conversation that your office could possibly provide some educational material on HIV & AIDs that I could use for a speech at my Toastmaster's Club. In case you aren't familiar with Toastmasters — ~~they~~ it is an international organization with a mission to help men & women learn the art of speaking, listening & thinking. The purpose of my speech will be to expand the knowledge of the audience about HIV & AIDs in a way that will be meaningful to them. Please send the material to me at the address below. Thank you Kristine & I hope you have a great week!

Sincerely,

Charlotte Lang
3180 Northwest Division, #219; Gresham, OR 97030 (503)(661-1396)

NOV - 5 1993

ASTHOFAX

Association of State and Territorial Health Officials
415 Second Street, N.E., Suite 200
Washington, D.C. 20002
PHONE: (202) 546-5400 FAX: (202) 544-9349

TO: Kristine Gebbie (632-1096)
Sandra Massenburg (690-7560)
Steve Lee (632-1096)

FROM: Margaret Skelley

DATE: November 5, 1993

COMMENTS:

Attached is pertinent information regarding our November 8 meeting.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
415 Second Street, N.E., Suite 200, Washington, D.C. 20002
(202) 546-5400

November 5, 1993

Kristine Gebbie, R.N., M.N.
National AIDS Policy Coordinator
750 17th St., N.W., Suite 1060
Washington, D.C. 20503

Dear Kristine:

On behalf of the Association of State and Territorial Health Officials (ASTHO), I thank you again for meeting with state and local representatives on November 8 from 1:00 p.m. - 4:00 p.m. to discuss state and local perspectives on key HIV/AIDS issues facing the nation. The following nine national organizations will be represented during the course of the meeting:

- Association of State and Territorial Health Officials (ASTHO)
- Association of State and Territorial Public Health Laboratory Directors (ASTPHLD)
- Association of State and Territorial Public Health Social Workers (ASTPHSW)
- Council of State and Territorial Epidemiologists (CSTE)
- National Alliance of State and Territorial AIDS Directors (NASTAD)
- National Association of State Alcohol and Drug Abuse Directors (NASADAD)
- National Association of State Mental Health Program Directors (NASMHPD)
- State Medicaid Directors Association (SMDA)
- U.S. Conference of Local Health Officers (USCLHO)

As the attached agenda details, from 1:00 p.m. - 2:30 p.m. you will be meeting with state and local health agency representatives to discuss several key HIV/AIDS public health issues. From 2:30 p.m. - 4:00 p.m., we will be joined by members and/or staff of national organizations representing state medicaid, mental health and substance abuse agencies for a discussion of "Health Care Reform and AIDS."

Attached for your information is the list of individuals who will be attending the meeting, as well as several recent ASTHO letters on health care reform which may provide useful background to our discussions.

ASTHO appreciates the opportunity to work collaboratively with your office to bring states together on these most important public health issues and we look forward to continuing this dialogue on a periodic basis.

Sincerely,

Margaret Skelley

Margaret Skelley
Project Director, HIV/AIDS

Tentative Agenda
MEETING WITH NATIONAL AIDS POLICY OFFICE
Old Executive Office Building
Indian Treaty Room (4th Floor)
November 8, 1993
1:00 p.m. - 4:00 p.m.

MEETING WITH STATE AND LOCAL HEALTH AGENCY REPRESENTATIVES

I.	INTRODUCTIONS	1:00 - 1:05
II.	MECHANISM FOR PERIODIC COMMUNICATION WITH STATES	1:05 - 1:20
III.	HIV PREVENTION COMMUNITY PLANNING	1:20 - 1:50
IV.	FY 95 BUDGET •HIV Prevention •AIDS Treatment	1:50 - 2:05
V.	QUESTIONS AND ANSWERS	2:05 - 2:30

crime bill - health services

JOINT HEALTH, MEDICAID, SUBSTANCE ABUSE, AND MENTAL HEALTH MEETING

VI.	INTRODUCTIONS	2:30 - 2:35
VII.	OVERVIEW OF NATIONAL AIDS POLICY OFFICE ROLE	2:35 - 2:45
VIII.	HEALTH CARE REFORM AND AIDS	2:45 - 3:30
IX.	QUESTIONS AND ANSWERS	3:30 - 4:00
X.	ADJOURNMENT	4:00

ATTENDEES TO NOVEMBER 8 MEETING WITH NATIONAL AIDS POLICY OFFICE

November 5, 1993

John Auerbach, M.B.A.
NASTAD Chair
Massachusetts Department of Health
AIDS Program and Health Resources
150 Tremont Street
Boston, MA 02111
(617) 727-0368
Fax (617) 727-6943

Dot Bon, M.S.W.
ASTPHSW
South Carolina Department of Health
2600 Bull St.
Columbia, SC 29201
(803) 737-3950
Fax (803) 737-3946

Bill Butynski, Ph.D.
NASADAD
444 N. Capitol St., Suite 642
Washington, D.C. 20001
(202) 783-6868
Fax (202) 783-2704

Barbara A. DeBuono, M.D.
Chair, ASTHO HIV Committee
Rhode Island Department of Health
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Providence, RI 02908
(401) 277-2231
Fax (401) 277-6548

Elizabeth Edgar
NASMHPD
66 Canal Center Plaza, Suite 302
Alexandria, VA 22314
(703) 739-9333
Fax (703) 548-9517

John W. Farrell, M.S.W.
NASADAD HIV Committee Chair
Div. of Alcoholism, Drug Abuse and Addiction Services
New Jersey Department of Health
CN 362
Trenton, NJ 08625-0362
(609) 292-9068
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Dave Fleming, M.D.
CSTE
Epidemiology
Oregon Health Division
800 N.E., Oregon St.
Portland, OR 97232
(503) 731-4023
Fax (503) 731-4082

Richard E. Hoffman, M.D.
CSTE
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Joe Kelly
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Washington, D.C. 20001
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Pat McInturff
USCLHO
Seattle-King County Department of Health
110 Prefontaine Pl., S.
Seattle, WA 98104
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Fax (206) 296-0208

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CSTE
North Carolina Department of Health, Environment and Natural Resources
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Raleigh, NC 27611
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Fax (919) 733-0513

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Sondra Nelson
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Lloyd Novick, M.D.
ASTHO
New York State Department of Health
ESP Corning Tower, Rm. 695
Albany, NY 12237
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James Pearson, Ph.D.
ASTPHLD
Div. of Consolidated Lab Services
Commonwealth of Virginia
1 N. 14th St., Rm 231
Richmond, VA 23219
(804) 786-7905
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California Department of Health Services
Office of AIDS
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Fax (202) 434-8092

Margaret Skelley
ASTHO
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Dennis Stover
NASTAD
Indiana State Board of Health
Division of Acquired Diseases
1330 W. Michigan St.
Indianapolis, IN 46202
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Fax (317) 633-0663

Seema Verma
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Dennis Whalen
NASTAD
New York State AIDS Institute
ESP Corning Tower, Room 359
Albany, NY 12237
(518) 473-7542
Fax (518) 486-1317

Loretta Williams
SMDA
810 First St., N.E., Suite 500
Washington, D.C. 20002-4267
(202) 682-0100
Fax (202) 289-6555

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
415 Second Street, N.E., Suite 200, Washington, D.C. 20002
(202) 546-5400

October 25, 1993

President William J. Clinton
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear President Clinton:

The Association of State and Territorial Health Officials (ASTHO) met this weekend with representatives of the National Association of State Alcohol and Drug Abuse Directors (NASADAD) to discuss our common concern that adequate resources for treatment of the alcohol and drug addicted be available under health care reform. Currently, twenty-five percent of all health expenditures are related to substance abuse; we are spending now $238 billion annually for conditions occasioned by substance abuse.

Since the efficacy of treatment services for patients with alcohol and drug abuse is well-established, ASTHO recommends that the policy of "treatment on demand" be adopted as a cornerstone of your health care reform effort. We further recommend the inclusion of comprehensive services for alcohol and drug abuse in the minimum benefit package. Unless specific initiatives are taken, it is estimated that only 50 percent of clients currently in treatment will be covered under health care reform.

In order to assure that these recommendations are enacted, we request that you commit to keeping the alcohol and drug abuse block grant in place. Furthermore, we recommend that you augment these funds by shifting the "out of country crop eradication" expenditure to the block grant for prevention and treatment services of the block grant.

Sincerely yours,

C Mahan MD

Charles S. Mahan, M.D.
President

mh

cc: Lee Brown, Ph.D.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
415 Second Street, N.E., Suite 200, Washington, D.C. 20002
(202) 546-5400

November 1, 1993

President William J. Clinton
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President:

The Association of State and Territorial Health Officials (ASTHO) represents the chief public health officials in the 50 states, the District of Columbia, and the U.S. Territories. We applaud the goals and design of the courageous health reform strategy that you and our First Lady will soon submit to Congress. In fact, we are busily preparing ourselves and our organizations to reinvent state health agencies to develop the accountability mechanisms needed both to monitor access, quality, and costs of health care, and to integrate and streamline public health services and outreach into the larger process.

We write you today to express our sincere and urgent concern about the need to fund states and governors adequately, both to bring the poor, the uninsured, the disenfranchised into the new system, and to assure that population-based public health and health education doesn't get lost, as always before, in the Congressional shuffle. We recognize that the funding priorities for small businesses, early retirees and deficit reduction in the reform effort have political merit. However, the most critically underfunded entities in the spectrum of competing constituencies are the states themselves.

States will need significant, as yet unidentified, resources to bring the at-risk populations into universal access. While there are significant efficiencies to be achieved in Medicaid, states are still woefully underfunded to effectively include the public assistance populations and the uninsured who will not be covered by an employer mandate into the proposed new system. Hawaii's real experience with an employer mandate indicates that the vast majority of small businesses can accommodate health insurance coverage of employees without subsidies. A means-test premium supplementation approach to small businesses in distress might free up 50 billion dollars to assist states and governors. Similarly, some of the 29 billion dollars proposed to be allocated to the National Health Board, alliances, and infrastructure set-up costs could be re-allocated to states without undermining the national effort, and while we are elated to learn of your support for significant additional funding to public health, we know from painful experience that such funding is unlikely to compete well against underfunded medical care needs.

Mr. President, we support you and recognize this letter likely seems presumptuous. However, we strongly advocate financing public health with at least 18 billion dollars of designated funding. We support re-allocating from planned subsidies an additional 50 billion dollars to states to bring the poor, the disenfranchised, and the unemployed into the alliances and new system with sufficient funding to make universal access an immediate reality.

As you and the First Lady have eloquently articulated, without universal acccess, we cannot have cost containment, and without an approach to universal access which emphasizes prevention, primary care, and public health, we will neither contain costs nor improve the health status of those most in distress.

We offer these suggestions with the full commitment to assist you in your efforts to advance reform. This includes using our membership to help convince the Congress as well as business and consumer constituencies that our goals should be theirs also.

Thank you for your consideration of these ideas.

Sincerely yours,

C. Mahan, MD.

Charles S. Mahan, M.D.
President

mh

cc: Donna E. Shalala, Ph.D.
Philip R. Lee, M.D.
M. Joycelyn Elders, M.D.

THE WHITE HOUSE

WASHINGTON

Steve
Please send 2
copy of this to
lead staff — &
2 blind for
copy to Patsy Fleming

November 5, 1993

MEMORANDUM FOR KEITH BOYKIN
SPECIAL ASSISTANT TO THE PRESIDENT

FROM: KRISTINE M. GEBBIE N. Steinhoff for
NATIONAL AIDS POLICY COORDINATOR

RE: STATUS OF GAY-RELATED ISSUES

You have inquired regarding the status of certain issues raised in a "Presidential Transition Document" from the National Gay & Lesbian Task Force. Our responses follow:

12. **Implement the recommendations of the National Commission on AIDS.**

The Office of the National AIDS Policy Coordinator staff has begun implementing the changes recommended, including the promotion of linguistic specific materials, programs for minors, needle exchange programs, programs for correctional facilities, and greater coordination of funding. Staff are currently reviewing all recommendations of the National Commission on AIDS and comparing them to recommendations made by other national and affected groups to identify other action steps.

13. **Appoint an AIDS czar.**

This recommendation has been fulfilled by the creation of this office.

14. **Ensure that any health care reform include funding for all AIDS services.**

The Administration's health reform proposal covers all critical AIDS services, especially after full inclusion of mental health and dental services. Continuation of the Ryan White Care Act to provide support services, in addition to the benefits package that all Americans will get, is also a part of the transition plan.

15. **Commit funds to find a cure for HIV and AIDS.**

Since the election, the Administration has increase research funding by 21 per cent to $1.3 billion dollars. The ONAPC has not only supported the research budget requests submitted by the National Institutes of Health (NIH), the Department of Defense (DOD) and the Department of Veterans Affairs (DVA), but has also been instrumental in causing funds to be redirected to efforts recognized by the research communities to be the best efforts for the costs. Such redirection has most recently taken the form of promoting redirection of the $20M in the DOD budget from single-phase gp-160 trials to multi-phased trials and the basic, underlying vaccine research necessary to developing vaccine trials. Further, the Administrations representative is participating in the Future Directions in AIDS Research (Madison/Harvard) Group which is exploring new ways to speed up AIDS research and treatment.

16. **Expand drug testing and clinical trials to include populations presently left out of such research.**

The number of women and minorities included in HIV research has been increasing in recent months. ONAPC, the Office of AIDS Research, and community constituency groups will continue to cooperate and coordinate to increase this participation.

18. **Encourage targeted and honest HIV prevention and treatment campaigns for all communities.**

Newly designed, and much more open CDC prevention messages are about to be launched. Beginning on January 1, 1994, the sole guidelines over content at the local level will be that the advertisements must be community sensitive and appropriate for the audience for whom they are intended.

19. **Fully implement the Americans with Disabilities Act.**

The ADA is proceeding on the timetables included in the legislation. ONAPC supports the aggressive enforcement of the provisions of the Act and is fully supportive of the actions of the Department of Justice's ADA enforcement group.

20. **Condemn policies that discriminate against people with HIV and AIDS.**

The Coordinator has spoken out, and will continue to speak out, in opposition to discrimination towards people with HIV and AIDS. She has specifically provided for staffing the

office with a person who is trained and proven in the areas of discrimination and confidentiality, and she has made proposals within the Administration regarding the issues of non-discrimination and confidentiality for people living with HIV/AIDS.

26. **Support school and community-based efforts to provide preventative education.**

The Coordinators office is fully supportive of the Surgeon General's proposals for school and community-based efforts to provide prevention education. This office is proposing video and other training methods to engage the support of the Parent Teachers Association and other school groups to begin such education. ONAPC is working with the CDC Office of Adolescence and School Health on several programs to impact school education including a survey on the contents of promotional health education materials.