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health, and primary care.

Committees, task forces, and affiliate organizations prepare reports and recommendations regarding ASTHO policy positions which are adopted by the Executive Committee.

Public Health Foundation

The Public Health Foundation was established in 1981 by ASTHO as the ASTHO Foundation and changed to its current name in 1985. The Foundation is a private, non-profit organization which monitors developments in public health and facilitates the exchange of information among public and voluntary health agencies, researchers and educators.

The Foundation supports ASTHO's work with research and information sharing projects, data collection and analysis, and education and training programs. Current Foundation projects include the Public Health Network (electronically linking more than 600 public health agencies), the ASTHO Reporting System (an annual analysis of uniform national data voluntarily provided to ASTHO by state health agencies), special reports on state public health programs and trends in public health activities, special studies on AIDS and block grant spending, management training, environmental health and conference management.

To maintain a strong link between the policies of ASTHO and the work of the Foundation, five members of the 11-member Foundation's Board of Directors are appointed by the ASTHO Executive Committee.

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August 1994

ASTHO

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Purpose

The Association of State and Territorial Health Officials (ASTHO) represents the directors of public health in each of the 50 states, the District of Columbia and the U.S. Territories and Possessions. The purpose of the Association is to formulate and influence, through collective action, the establishment of sound national public health policy and to assist and serve state health departments in the development and implementation of state programs and policies for the public's health and the prevention of disease.

History

ASTHO's roots go back to 1884 and the Conference of State and Provincial Health Authorities of North America where ideas and information were exchanged. With the adoption of the Social Security Act of 1935, state health officials expressed the need for a separate organization to deal with the distribution of federal funds among states which was of no interest to Canadian members. ASTHO, as it is currently organized, was incorporated on March 23, 1942 as a resource for its members, Congress, the Administration, other national organizations and the general public. Its interests and activities are wide ranging and include scientific, educational, programmatic and legislative issues.

Membership

Membership in ASTHO is limited to the executive officer of the department of health of any state, Territory or Possession of the United States. Because of its membership, ASTHO's influence and activities reflect the major positions and concerns of the state health departments. ASTHO is governed by a ten member Executive Committee and is supported by a committee and task force structure whose members work on particular issues that affect the association and state health agencies.

Affiliates

ASTHO engages the expertise of a formally linked network of organizations dedicated to representing the concerns of state health departments. There are currently seventeen affiliated groups which represent directors of divisions within the state health departments and include Nutrition, Maternal and Child Health, Dental, Laboratory, Epidemiology, AIDS, Nursing, Vital Records and Health Statistics, Public Health Education, Health Facility Survey Agencies, Vector Control, Chronic Disease, Risk Assessment, Social Work, Local Liaison and Public Health Information and Emergency Medical Services. These associations function independently yet cooperate very closely with ASTHO to develop and promote sound public health policy.

Policy Development

ASTHO's professional policy development staff works with states to formulate and present collective public health positions and recommendations to the Congress, the Administration and other national organizations. Under Executive Committee guidance, ASTHO staff formulates public health advocacy positions and coordinates testimony on key legislative issues of national interest.

ASTHO conducts numerous projects, some funded by federal agencies, to promote public health program development at the state level. These cooperative projects are guided by ASTHO committees and address a variety of key public health issues. These projects provide information to states by developing surveys and reports on such issues as state immunization costs, state tobacco policies and activities, state AIDS activities, primary care, minority health, state activities on indoor air pollution and the environment. The results of these reports are utilized by ASTHO in the development of public policy and are shared with Congress and the Administration.

ASTHO staff also serves as an informational resource to state agencies on public policy developments. Specifically, ASTHO circulates the Washington Report, an update of legislative activities and informational items, to ASTHO members, the Washington Offices of the Governors and throughout the public health community. To facilitate communication among the states and between state and federal agencies, ASTHO has established networks of health department contacts on issues such as environmental health, tobacco use, primary care and HIV/AIDS.

ASTHO policies which are adopted by the Executive Committee are generated through position statements and resolutions from ASTHO members and affiliate groups, legislative review, committee statements, endorsement of public health coalition statements and consensus conference recommendations.

Committees

ASTHO's committees and task forces focus on a variety of public health concerns including environmental health, immunizations, health care finance, HIV/AIDS, injury control, tobacco, minority

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PRINCIPLES ON HEALTH CARE REFORM AND HIV/AIDS

Capacity to provide comprehensive, low cost, high quality services to vulnerable populations such as persons with HIV/AIDS should be the definitive criterion or "litmus test" against which any proposal to reform the Nation's health care system must be evaluated.

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APRIL, 1994

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

TESTIMONY ON REAUTHORIZATION OF RYAN WHITE

PRESENTED BY

BARBARA A. DEBUONO, M.D., M.P.H.

TO

THE RYAN WHITE CARE ACT FUTURE PROGRAM DIRECTIONS AND REAUTHORIZATION SUBCOMMITTEE OF THE HRSA AIDS ADVISORY COMMITTEE

DECEMBER 15, 1993

REAUTHORIZATION OF RYAN WHITE
ASTHO PERSPECTIVES

December 15, 1993

I am Dr. Barbara DeBuono, Director of the Rhode Island Department of Health, here today speaking on behalf of the Association of State and Territorial Health Officials (ASTHO), which represents the chief health officer from each of the 50 states, the District of Columbia and the U.S. territories. My colleague from Illinois, Dr. John Lumpkin, who represents ASTHO on the HRSA AIDS Advisory Committee, regrets that he could not be here to join us today. I will begin by addressing some general aspects of the legislation and will offer some recommendations for significant restructuring as well as discussing issues for consideration within the context of health care reform. I would also like to emphasize that our affiliate, the National Alliance of State and Territorial AIDS Directors (NASTAD), also represented here today, is undertaking a special project over the next few months whereby information on reauthorization issues will be collected via regional meetings with states, localities and communities throughout the country. ASTHO is supportive of this effort and looks forward to the contribution these findings will make to the reauthorization process.

First, I must stress that states strongly endorse continuity of federal resources for planning and delivery of HIV/AIDS medical and support services for persons with AIDS. Although initially the Ryan White CARE Act simply replaced previous categorical funding streams to states with a single stream of funds under Title II, increases over the past two years in Title II resources have enabled states to significantly enhance their care systems for HIV infected persons. Specifically, Title II CARE funds have resulted in establishment of over 300 care consortia in 42 states, provision of AIDS therapeutics in every state and territory, extension of health insurance for persons with AIDS, and expansion of more cost effective alternatives to inpatient treatment such as home-and community-based care services. The Ryan White CARE Act has been vital to increasing state capacity to respond effectively to an epidemic which respects no racial, ethnic, geographic, cultural, or socioeconomic boundaries.

In considering reauthorization of this landmark legislation, it is important to first fully recognize some of the significant changes that have occurred relative to the epidemic since original passage of the Ryan White CARE Act in 1990. Geographic and demographic shifts in the HIV epidemic, new research findings on the efficacy of different interventions, migration in and out of communities, greater variability among service providers in the capacity to deliver the mix of services needed by HIV infected persons; periodic restructuring of federal, state and local governments; the increasing longevity of persons with AIDS (PWAs), the increasing complexity of related epidemics of TB, STD and substance abuse; and the multitude of newly established community-based organizations and service providers are all factors that converge to make a highly complex and dynamic system. Reauthorization provides a unique opportunity to respond to this dynamism; discussions of the future financing and delivery of HIV/AIDS care **must** be based on this dynamic system rather than on what is perceived to have been the original intent of Congress back in 1990. Ultimately, reauthorization issues must be considered in the context of a reformed health care system.

Although the current language in the Ryan White CARE Act of 1990, P.L. 101-381, will guide the programs through FY 1995, the following recommendations should be considered during reauthorization for FY 96 and the future:

STATE HEALTH AGENCY ROLE

▪ **The legislation should more clearly reflect the role and authority of state and local public health agencies.** As the guarantors of the public health[1], these agencies are accountable for administration, coordination and oversight of all publicly funded health programs. The state and local public health role is essential to assure availability of services for all while guarding against duplication of effort and misdirection of resources. Ryan White funding streams should reflect these crucial roles while empowering communities to be actively and substantively involved in identification and prioritization of their respective needs.

▪ **Reauthorizing language should reflect the fact that state health agency "constituents" are whole state populations.** Unique to state and local health agencies is their capacity to assure services for the **entire** population--including disenfranchised individuals who may not be formally represented by a community-based or national organization, or who may not even have access to a service provider. Public health's responsibility for the entire population, including the homeless, parolees, mentally ill substance abusers, migrant persons and other underserved populations, removes the focus from a single segment of the community to assurance of services for all. It is this very responsibility that has led states to redistribute their state and federal funds to assure services for all residents across the state. This responsibility, which is consistent with the legislation's requirement for states to balance the needs of urban and rural areas, has also underscored the states' forceful arguments for parity across their jurisdictions.

▪ **The disparity of care received by PWAs across Titles on the basis of geography must be corrected.** Disproportionate services and access for those services in Title I cities is contrary to the statutory role of public health agencies to provide services for all. The fact that at least seven Eligible Metropolitan Areas contribute Title I funds to Title II states for AIDS drug assistance programs only evidences the faulty distribution of resources between the two Titles. This issue is particularly salient given that citizens in 33 states, or well over half of the nation, are ineligible for the services provided by Title I cities simply by virtue of their residence.

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[1] Healthy Communities 2000 Model Standards: Guidelines for Community Attainment for the Year 2000 National Health Objectives; Third Edition, 1991; p.1.

- Between 1986 and 1992 states have contributed over $1 billion in state general revenues to combat HIV/AIDS. In some instances, these significant resources far exceed those appropriated by the federal government. **In order to assure that both the federal and state public dollar is being spent judiciously, reauthorization language should provide states with final accountability for resource coordination and allocation.** Currently, because Title I funds are not appropriated to official health agencies, state and local health agencies are held accountable for treatment programs for which they have no recognized authority.

- **A strong mechanism to involve states in early intervention funding to nongovernmental entities under Title III(b) should be identified and included in reauthorizing language.**

FEDERAL ROLE

- **ASTHO recommends that HRSA work collaboratively with grantees to develop regulations that provide the flexibility necessary to respond effectively to the diversity of needs and populations across the country.** Current administration of the Act relies too heavily on the application process as an alternative to establishing regulations or policy.

- **Formal mechanisms should be established to assure effective coordination among HRSA bureaus administering different Titles of the Ryan White CARE Act.**

- **HRSA's oversight role should be expanded to permit the agency flexibility in responding to unique issues affecting grantee capacity to administer the Ryan White CARE Act.**

- **HRSA should enforce requirements in the Act for Title I and Title II plans to be "compatible with any existing state or local plan[2]."**

GENERAL ISSUES

- **Planning council and consortia membership should reflect the epidemic.** Specific, prescriptive requirements for membership on these bodies has not lead to a widespread perception of representativeness as was likely the intent of the legislation. Both persons with AIDS as well as constituents of the National Minority AIDS Council (NMAC) have repeatedly reported difficulties in participation and representation on planning councils and consortia. Further, such rigid categorization of individuals required for service on planning councils and consortia simply do not reflect the realities faced in low incidence or rural areas of the country.

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[2] Ryan White Comprehensive AIDS Resources Emergency Act of 1990; P.L. 101-381; Sec. 2602(b)(3)(B).

- Data collection should be limited to aggregate reporting of Ryan White funded services only. Careful attention must be given, even in collecting aggregate data, to prevent duplicate counting of those served with Ryan White dollars. Quarterly reports and data collection instruments should be clear, consistent, and based on discrete categories of data only.

- **Reauthorization language should preclude providers competing for funds from involvement in decisionmaking or planning that influences those same funds.** The current system is too often driven by conflict of interest rather than by objective fiscal management.

FUNDING, SET-ASIDES, FORMULAS

- **ASTHO recommends one consistent formula for awarding AIDS treatment funds. Federal funds should not be awarded on the basis of deceased individuals and should protect grantees against fluctuations in funding based on minor changes in reported cases. All grantees should be equally accountable for requirements for matching funds and consideration should be given to using a percent increase in cases over a fixed period as one factor in the formula.**

- **The threshold for eligibility of Title I cities should be based on live cases.** Basing eligibility for federal funds on current cases enables the country to target its public dollar on treatment services for persons living with AIDS as opposed to continuing a remuneration system for geographic areas most heavily affected since the beginning of an epidemic.

- **Grantees should be permitted to expend a greater percentage of funds for administering Title II of the Ryan White CARE Act.** A recent ASTHO survey[3] clearly demonstrated the inadequacy of the 5% cap for "administration, reporting, accounting and program oversight functions[4] and highlighted the fact that states must divert resources from other federal agencies to administer the CARE Act. Most frequently states utilize resources intended for HIV prevention to administer Title II of Ryan White. This is an unacceptable means of implementing a federal program and **ASTHO recommends that HRSA consider using CDC's HIV Prevention Cooperative Agreement as a model for ensuring grantee accountability while recognizing that management is a necessary component of the program and should be adequately provided for within the grant.[5]**

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[3] ASTHO. HIV/AIDS Technical Assistance Needs of State Health Agencies: A Report to HRSA, 1993. p. 8.

[4] Ryan White Comprehensive AIDS Resources Emergency Act of 1990; P.L. 101-381; Sec. 2618(c)(4).

[5] CDC's HIV Prevention Cooperative Agreement does not mandate a specific administrative cap for grantees, but instead, recognizes the cost of administration is inherent in successful program implementation.

- Given that research has estimated the lifetime per patient cost from time of HIV infection until death at $119,274[6], ASTHO recommends that the minimum Title II award be increased substantially from $100,000. **All states and territories should receive at least $200,000 to permit them to provide a continuum of care to persons with HIV/AIDS.**

- **Grantees should be permitted to expend a greater percentage of funds for planning and technical assistance.** Five percent is inadequate to effectively plan for Title II programming and to provide the necessary technical assistance to consortia and state grantees.

- **Special Projects of National Significance funding should remain a priority, but should be restructured to prevent depletion of funds from a single Title of the Act.** In addition, **HRSA should be subject to requirements for periodically summarizing and disseminating outcomes nationally.**

- A fixed 15% set aside for women, children and families has not been uniformly effective in assuring services to those populations; **a 'one-size-fits-all' approach is often not applicable across the diverse regions and needs throughout the country.** "Some areas need 15% for women, children and families; others need more; and others need less. The allocation of funding should be based on that need rather than on a fixed percentage and the consortia should be charged with allocating funds according to local need."[7]

- **Mechanisms to support early intervention, which do not divert resources from primary prevention, should be explored during reauthorization.**

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[6] Hellinger, FJ. "The Lifetime Cost of Treating a Person With HIV." JAMA, July 28, 1993; 270:474-478.

[7] Ryan White National Organizations Discussion Group Meeting, September 9, 1993, p.173.

ADMINISTRATIVE CENTRALIZATION

▪ A recent AIDS Action Foundation report asserts that "...the language and the structure of the Act itself permits--even facilitates--the playing out of any existing tensions through the dual structures created under the Act."[8] Resolution of disputes and clarification of roles among the multiple entities involved in administering the Ryan White CARE Act--governments, grantees, Title II consortia, Title I planning councils, and elected officials--have diverted critical energies from the overall intent of providing treatment services to HIV infected persons. Additionally, the structure of the Act requires that resources be devoted to preventing duplication of planning, needs assessment and service delivery activity between Titles, further depleting the limited resources available for providing and coordinating care for HIV/AIDS. States believe that the nation must carefully consider the potential magnification of this diversion of resources as the number of Title I cities increases to the point where the entire nation is constituted of independently-operated Title I cities. **ASTHO recommends that consideration be given to administratively centralizing all Titles of the CARE Act with accountability resting at the state level. Such a mechanism would provide the necessary centralized accountability and would recognize the essential roles of state and local public health, while providing continuity for existing grantees. Set asides for current grantees, based on demonstrated need, would be determined collaboratively by a statewide advisory body and the state health agency within the context of parity for persons requiring services across a given state. ASTHO's affiliate, NASTAD, will gather input on issues related to the structure of the Act during the regional meetings planned over the next few months.**

ALTERNATIVES TO ADMINISTRATIVE CENTRALIZATION

▪ Separate appropriations for the various Titles has resulted in competition rather than cooperation and has significantly exacerbated disparity of services for HIV infected persons. It has been suggested that such competitive relationships may have even precluded sharing of information among grantees and, in some instances, state health agency participation on Title I councils.[9] **At a minimum, a single authorizing funding level across Titles is crucial to providing incentive for grantees to work collaboratively to achieve the common goal of providing services to HIV infected persons.** Under such a scenario, all individual Titles would continue to be administered separately, but within a single authorizing and appropriating level.

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[8] Roger Doughty; Lessons From the First Two Years: Issues Arising In the Implementation of Ryan White CARE Act Titles I and II. 1993. p.21

[9] Roger Doughty; Lessons From the First Two Years: Issues Arising In the Implementation of Ryan White CARE Act Titles I and II. 1993. p.15

▪ **Consideration should be given to using the concepts of the CDC HIV prevention community planning process as a template for HIV treatment planning.** Such an approach would empower communities to identify and prioritize needs, while preserving the authority of official public health agencies for final plans and resource allocation. All states would be required to assure a representative process for community input into planning. Options might include utilizing an existing planning body reflecting the epidemic; establishing or enhancing a statewide consortium; merging care planning with the existing HIV prevention body(ies); or some combination thereof. Grantees would be accountable for developing mechanisms to protect against conflict of interest and to resolve disputes.

▪ **The reauthorizing language should require joint or coordinated planning and needs assessments between Titles I, II and III(b).** Merging of separate planning council and consortia functions of Title I and Title II has already been implemented to various degrees in places such as Seattle-King County and San Francisco.

▪ **Applications, needs assessments, budget cycles, provision of technical assistance, quarterly progress reporting and data collection requirements should be synchronized across all Titles to permit maximum integration and coordination of efforts.**

RECOMMENDATIONS SPECIFIC TO HEALTH CARE REFORM

▪ **Categorical funding of Ryan White programs should continue to be a priority for Congress at least until 1998, when transition into a reformed health care system is expected to be completed, and until data systems are operational and can document that populations previously served by Ryan White are adequately covered under the new health care system.** Consideration might be given to reauthorizing the Act for a limited time period to include the transition to a new health system.

▪ According to the National Association of People With AIDS (NAPWA), the top three needs of persons with AIDS are: financial, health insurance and access to medicines [10]. Two of these priority needs, access to medications and health insurance, are currently addressed, in part, through Title II funds to states. Health care places fourth in the list of needs and is provided to eligible persons through all four Titles of the Act. All three of these needs have a high likelihood of being at least partially covered within The Health Security Act. **A study should be conducted to accurately determine the extent to which these services may not be covered under health care reform. Supplemental funds must be made available to ensure adequate coverage for those services determined to be inadequately covered in the Health Security Act.**

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[10] HIV In America: A Report by the National Association of People With AIDS, 1992, p.22.

- The President's Health Security Act will not cover undocumented aliens[11]. These individuals will continue to obtain their care from the public system of state and local health departments. **Ryan White funding will be critically needed to enable public health agencies to meet the continuing service needs of undocumented populations.**

- **With the frequency of off-label applications of drugs for AIDS therapy and the potential that such uses may not be adequately covered in the Health Security Act[12], consideration should be given to retaining state AIDS drug reimbursement programs to provide coverage for alternative therapies and for off-label application of prescription drugs.**

- **The CARE Act should be refocused to address the range of non-medical care and support services such as counseling, eligibility services, case management, etc., which are essential to persons with AIDS and may not be fully covered within health care reform.** This is especially true of non-medical early intervention services such as counseling for those just learning of a positive serostatus; prevention of opportunistic infections, prevention of sex and needle sharing partners from becoming infected, and other services not currently classified as "enabling services[13]" under the Health Security Act.

- Substance abuse and mental health services are currently among the most vulnerable in the Health Security Act. Absent full coverage for these services within health care reform, PWAs cannot be assured adequate HIV/AIDS care. **Mental health and substance abuse services are essential supplements to HIV care and must continue to be funded separately unless they are adequately incorporated into health care reform.**

- According to HRSA's February 1993 briefing to Dr. Shalala on HIV/AIDS care[14], Title II Care Grants to States for FY 1991 (presumably the most recent data available) were expended as follows: 50% Consortia Development; 37% Drug Therapies; 8 % Administration and Program Evaluation; 3 % Home Health; 2 % Insurance Continuation. **Further analysis of consortia development, which consumed 50% of Title II funds in FY 1991, should be conducted to determine whether additional funding will be required to supplement resources which may be provided within the Health Security Act.**

- **Clarification of "essential service providers[15]" should be provided to determine if Ryan White CARE providers and consortia may be categorized as "essential" for the 5 year period described in the legislation.**

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[11] The Health Security Act (S.1757) Title I Subtitle A, Sec. 1005(a); p.17

[12] The Health Security Act (S.1757) Title I Subtitle B, Sec. 1122; p.67

[13] The Health Security Act (S.1757) Title III Subtitle E, Subpart D, Sec. 3461(b); p.606.

[14] G.S. Bowen, M.D., Associate Administrator for AIDS; Briefing for Secretary Shalala on AIDS/HIV Care. Programs of the Health Resources and Services Administration; February 2, 1993.

[15] The Health Security Act (S.1757) Title I Subtitle E, Part 3, Sec. 1431-32 p.249-255

THE REAUTHORIZATION PROCESS

▪ **HRSA should continue to work with grantees throughout the reauthorization process and should play an active role in convening groups which may develop conflicting perspectives on the best mechanisms for reauthorization.**

▪ Lastly, in addressing key policy areas related to reauthorization, **HRSA should compile, integrate and broadly disseminate findings from the following efforts related to reauthorization:**

- Today's public hearing.
- Roger Doughty's background report to AIDS Action Council, "Lessons From the First Two Years: Issues Arising In the Implementation of Ryan White CARE Act Titles I & II", completed under HRSA contract. (Phone: (415) 255-0701)
- Jennifer Antico's report from the Inspector General's review of Ryan White conducted in June, 1993.
- Findings from HIV in America: A Report by the National Association of People with AIDS
- Findings from the following discussion groups convened by HRSA:

PLWAs	June, 1993
Title I	July, 1993
Title II	August, 1993
Titles I and II	August, 1993
National Organizations	September, 1993

- Findings and recommendations from the November 15-19 Ryan White grantee meeting.
- Findings from ASTHO's HIV/AIDS Technical Assistance Needs of State Health Agencies: A Report to HRSA.
- Findings from NASTAD's regional meetings on reauthorization of Ryan White planned for late 1993 and early 1994.
- Findings from the following HRSA reports:
  - First Year of AIDS Service Delivery Under Title I of the Ryan White CARE Act
  - State Responses to Title II of the Ryan White Comprehensive AIDS Resources Emergency Act
  - Development of Special Projects of National Significance (SPNS)
  - An Analysis of the Greater Baltimore HIV Services Planning Council
  - T.A. Topic Papers 1-5:
    - Managing the Conflict of Interest;
    - Health Insurance Programs for Persons with AIDS/HIV Disease; Conducting a Step-wise Assessment of Unmet Service Needs Yielding Quantifiable Results;
    - Housing and Residential Services for People with HIV/AIDS; and
    - Home Care for People with HIV Disease

States look forward to working collaboratively with HRSA to assure that, through the reauthorization process, the best possible HIV care systems can be put in place throughout the nation. Thank you for the opportunity to comment.

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STATE HEALTH AGENCY

VISION

FOR

HIV PREVENTION

Association of State and Territorial Health Officials
National Alliance of State and Territorial AIDS Directors
Council of State and Territorial Epidemiologists

November, 1993

HIV/AIDS

Through a cooperative agreement funded by the Centers of Disease Control and Prevention (CDC), ASTHO develops HIV/AIDS related policy, tracks and responds to national HIV/AIDS policy debates and legislative initiatives, and works collaboratively with affiliate organizations to address issues surrounding the development and implementation of national HIV/AIDS programs. The goal is to maintain strong working relationships with federal agencies concerning HIV policies through periodic meetings with Federal officials and development of ASTHO policy recommendations for ASTHO to present to Congress and the Administration.

MAJOR ACCOMPLISHMENTS

During the past year the ASTHO HIV/AIDS project followed a variety of HIV/AIDS issues and legislation, including: health care reform, FY 94 and FY 95 appropriations, reauthorization of the Ryan White CARE Act, development of HIV prevention community planning guidelines, home sample collection for HIV testing, revisions to the Healthy People Year 2000 HIV Objectives, the impact of prescription drug and drug paraphernalia laws on HIV prevention, newborn screening for HIV, the Veterans Health Care Act discounted drug program, the CDC Prevention Marketing Initiative, and World AIDS Day planning activities.

State health officials participated in the eight month External Review of CDC's HIV Prevention Strategies, and served on the HRSA's AIDS Advisory Committee, the PHS Interagency Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of HIV, and the Institute of Medicine Committee to Study HIV Transmission Through Blood Products. ASTHO also delivered testimony at CDC's Public Hearing on HIV prevention community planning, HRSA's public hearing on reauthorization of the Ryan White CARE Act, and the FDA Blood Products Advisory Committee hearing on HIV home sample collection kits.

The ASTHO HIV/AIDS Committee actively presented state health department perspectives through meetings with federal agencies including CDC, the National AIDS Policy Office, HRSA and other PHS agencies. ASTHO also coordinated a meeting of state health, substance abuse and mental health officials with the National AIDS Policy Coordinator and provided funding for ASTHO, the National Alliance of State and Territorial AIDS Directors, the United States Conference of Local Health Officials, and the National Association of County Health Officials representatives to attend the meeting of the CDC Advisory Committee on the Prevention of HIV Infection at which the External Review findings were released. In April, ASTHO published *Principles on Health Care Reform and HIV/AIDS*, which emphasized the crucial role of public health in combatting the AIDS epidemic and identified key HIV prevention and treatment needs in a reformed health system.

ASTHO also worked collaboratively with affiliates on a variety of HIV/AIDS projects including the *"State Health Agency Vision for HIV Prevention"* and an assessment of state AIDS directors conducted in August, 1993. Assessment findings were published in two reports: *"Effective HIV Prevention Community Planning: An Assessment of State Initiatives"* and *"A Resource Guide to Selected Outcome, Impact and Economic Evaluations of State and Local HIV Prevention Programs."* Efforts on these and other key HIV/AIDS issues were conveyed to states, national health organizations and Governors' Washington offices through the monthly *ASTHO HIV/AIDS Update* newsletter.

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HIV/AIDS UPDATE

Volume 5 Number 8 August 1994

ASTHO HIV/AIDS INITIATIVES

During the month of August ASTHO engaged in the following HIV-related activities on behalf of states:

- Attended the CDC HIV/STD Grantees meeting
- Sent joint ASTHO NASTAD letter to Senator Kennedy opposing mandatory HIV testing of pregnant women.
- Convened meeting with NASTAD staff and the Office of Drug Pricing to discuss state enrollment in the Veterans Health Care Act discounted drug program.
- Met with NASTAD Chair and National Association of People With AIDS staff to discuss state health departments efforts surrounding cryptosporidium in public drinking water.
- Attended a meeting of the Secretary's Advisory Committee on Infant Mortality to hear PHS plans to develop and implement recommendations from the NIH 076 trial.
- Attended meetings of the National Organizations Responding to AIDS and the Women and AIDS coalitions.
- Signed on to a coalition letter opposing restriction of local determination of educational programs and curricula.
- Met with staff from ASTHO affiliates, NASTAD and AMCHP, to discuss collaborative efforts.

LEGISLATIVE AND POLICY UPDATE

RECOMMENDATIONS FOR REDUCING PERINATAL TRANSMISSION OF HIV The August 5th issue of the *MMWR* contains recommendations for use of zidovudine (ZDV) in reducing the risk of perinatal transmission of HIV. The treatment recommendations were developed by a Public Health Service Task Force, which was assembled after results from AIDS Clinical Trials Group Protocol (ACTG) 076 trial demonstrated that zidovudine administered to a selected group of HIV-infected pregnant women and their infants can significantly reduce the risk of perinatal HIV transmission. Special thanks to **Dr. Barbara DeBuono, Director** of the **Rhode Island** Department of Health, and **Dr. George Rutherford, State Health Official** of **California** who served as consultants to the task force. The *MMWR* contains six general recommendations for treatment options for HIV-infected pregnant women and their newborns. It also discusses medical monitoring for pregnant women and neonates receiving ZDV and potential long-term effects for mothers and infants who have received ZDV. The Public Health Service has developed a plan for mass dissemination of the recommendations both nationally and overseas. State health departments should have already received copies. Additional copies may be obtained free of charge from the National AIDS Clearinghouse (1-800-458-5231).

As part of the federal response to the ACTG 076 results, HRSA is expected to convene a meeting of providers and public health leaders on September 19-20 to discuss implementation of the new treatment guidelines for HRSA funded projects and primary care sites. Meeting

participants will assist HRSA in developing a comprehensive strategy for: a) expanding HIV counseling and testing for women in clinical settings; b) implementing zidovudine therapy during pregnancy; and c) providing follow-up care for women, children and families affected by HIV/AIDS. ASTHO member **Dr. John Lumpkin, Director of the Illinois Department of Health** will attend the meeting and will lead a work group entitled "Developing and Planning Systems of Care."

CDC is charged with taking the lead on development of new counseling and testing guidelines for pregnant women. The agency is expected to publish a *Federal Register* notice to solicit comments for the development of these recommendations which are expected to focus on voluntary counseling and testing and consent issues. ASTHO will provide additional information as it becomes available.

On a related note, the FDA Antiviral Drugs Advisory Committee recently voted unanimously to recommend approval for the use of AZT to reduce the risk of HIV transmission from mother to infant. The committee's recommendation, while not binding, will be considered by the FDA in its review of the Burroughs Wellcome application to market its product "Retrovir," for use in preventing perinatal transmission of HIV.

ACTING AIDS CZAR APPOINTED Patsy Fleming, Special Assistant to Secretary Shalala, will serve as the acting National AIDS Policy Coordinator until a permanent replacement is found for Kristine Gebbie, whose resignation became effective earlier this month. Fleming has been actively meeting with representatives from national AIDS organizations and will meet with State health officials on the ASTHO HIV/AIDS Committee next month.

SURGEON GENERAL ADDRESSES NORA COALITION Surgeon Jocelyn Elders, M.D. was the keynote speaker at a recent National Organizations Responding to AIDS Coalition meeting, of which ASTHO is a member. Elders emphasized that HIV disease "involves multiple behaviors, such as teenage pregnancy, drug and alcohol use, and smoking, all of which come together to create the problem of HIV." Elders called for the AIDS community to forge partnerships with the educational community so that HIV prevention efforts for adolescents are part of a comprehensive approach to school based disease prevention and health promotion. The Surgeon General noted the rising incidence in TB and STDs, and stressed the importance of universal health care for all Americans.

CRYPTOSPORIDIUM CAUSES CONCERN Recent reports of cryptosporidium contamination in public water systems has lead to increasing concern among state health departments and the communities they serve. Reports that a recent Milwaukee drinking-water crisis, attributed to cryptosporidium, may have contributed to the death of several persons infected with HIV, have gained national attention and caused the AIDS community to call for the Environmental Protection Agency (EPA) regulation of drinking water to include provisions for cryptosporidium.

Human infection with cryptosporidium was first documented in 1976. Since that time, cryptosporidium has been recognized as a cause of gastrointestinal illness in both immunocompetent and immunodeficient persons While EPA testing for cryptosporidium is not currently required, effective in December 1994, EPA regulations will begin such testing for public water supplies.

However, with the many gaps in knowledge surrounding crypto, authorities contend that merely testing for the presence of crypto will not lead to a safer water supply, and may cause public alarm. Presently, it is unclear at what levels crypto in drinking water is dangerous to humans. Furthermore, authorities note that ingestion of crypto does not definitively lead to disease manifestation in the general population or in those that are immunocompromised. Scientists have also expressed uncertainty regarding the life cycle of cryptosporidium and its interaction with human hosts, and are calling for further studies.

State health departments have been actively involved with the crypto issue. ASTHO affiliate, the Council of State and Territorial Epidemiologists (CSTE) has called for CDC to hold a meeting on cryptosporidium. CDC scheduled such a meeting on September 22nd-23rd. **Michael Osterholm, Ph.D., Minnesota State Epidemiologist,** will represent ASTHO and CSTE at the meeting. Similarly, ASTHO affiliate, Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) called on EPA to hold a separate conference on the measurement and assessment of the public health threat from cryptosporidium.

In Washington, legislative efforts of public health organizations and the National Association of People With AIDS have been aimed at ensuring that the Safe Water Drinking Act, currently being reauthorized, includes a deadline for imposing standards for cryptosporidium. ASTHO has endorsed the Senate version of the Safe Water Drinking Act which imposes a timeline for developing standards for crypto, among other contaminants, regulation.

APPROPRIATIONS UPDATE In anticipation of an amendment calling for disclosure of newborn HIV screening results, ASTHO and NASTAD sent a joint letter to Senator Kennedy (D-MA), Chair of the Labor and Human Resources, opposing mandatory HIV testing of pregnant women, and expressed concern that such measures may deter women from seeking prenatal care. States were fortunate in heading off the issue of newborn screenings before it surfaced during Senate consideration of HHS appropriations. An amendment proposed by Senator Jesse Helms (R-NC), that makes the intentional spread of the HIV virus a federal offense did pass the Senate.

The final Senate bill recommends a $15 million increase for CDC HIV prevention programs, which falls significantly short of the $63 million increase called for by the House. However, the Senate did approve a $15 million increase for Ryan White CARE Act Title II programs, which is $3 million over the House recommendation. The House-Senate conference to resolve these differences will take place after Congress reconvenes on September 12.

RYAN WHITE REAUTHORIZATION UPDATE Although, the Ryan White CARE Act is currently authorized through 1995, many national organizations have endorsed an expedited reauthorization of the Act. Legislative sources indicate that Senate staff are in the process of drafting legislation that would reauthorize the Ryan White CARE Act during this legislative session, however a bill has not yet been introduced. Recent discussions at meetings led by the Four-Title Coalition, representing Titles I-IV of the Ryan White CARE Act, have indicated nonconsensus among national AIDS organizations on several key Ryan White issues, including representation on planning councils and consortia, and funding formulae.

On a related note, following a request from Senator Nancy Kassenbaum (R-KS), the General Accounting Office is in the process of preparing two separate reports on Ryan White reauthorization issues. The first report will examine access and parity issues, and the second will study the funding formulae. The reports are not expected to be published until next year. ASTHO will meet with GAO researchers next month and will provide additional information as it becomes available.

STATE NEWS

MARYLAND NEEDLE EXCHANGE PROGRAM BEGINS After an arduous three year political debate, the city of Baltimore has been granted an exemption from Maryland's prescription drug and drug paraphernalia laws and has begun a needle exchange program. The new program will also provide funding for drug treatment. The three year pilot program was approved by Maryland State Legislature and the Governor last year, largely through the intense lobbying effort of the city and state health departments. Dr. Peter Beilenson, the Baltimore City Health Commissioner, a key player in the legislative battle noted that in the first week of operation, without any advertising approximately 1000 needles were exchanged. For more information contact Dr. Peter Beilenson at (410) 693-4387.

NATIONAL NEWS

DISCOUNTED DRUGS AVAILABLE TO STATE HEALTH DEPARTMENTS ASTHO convened a meeting with NASTAD staff and the Public Health Service's Office of Drug Pricing to discuss state enrollment in the discounted drug program. The program enables public health "entities" to receive discounts on prescription drugs of up to 20-25%, similar to those discounts offered by state Medicaid programs. Any health department that receives federal funds for programs that purchase prescription drugs, or that provides funding to entities that purchase drugs, is eligible to participate. Among the covered entities of interest to AIDS programs are:

- State operated AIDS drug purchasing programs
- All AIDS clinics receiving Title XXVI assistance
- Comprehensive Hemophilia treatment centers
- Outpatient early intervention services for HIV
- Tuberculosis treatment facilities
- STD clinics

Currently, the AIDS drug purchasing programs of **Arizona, Florida, Hawaii,** and **New Mexico** are participating in the program. Depending on states' method of purchasing drugs, participation in the discount program may only require submitting a Medicaid pharmacy number to the Office of Drug Pricing. States are strongly encouraged to explore this option of purchasing drugs. For further details contact Captain William Matthews at the Office of Drug Pricing (301) 594-4353.

CDC STD/HIV PREVENTION GRANTEES MEETING ASTHO staff was among the 300 people representing health departments and AIDS organizations convened in Washington D.C. for the CDC Division of STD/HIV Prevention week-long grantees meeting. Through a series of plenary sessions and workshops, the meeting provided a forum for CDC representatives and grantees to discuss STD and HIV prevention efforts. This year's meeting focused on the challenges of HIV prevention, identifying successful prevention strategies, planning and evaluating STD/HIV prevention programs, the interaction between STDs and HIV, and the future directions of prevention efforts.

POSSIBLE HOSPITAL TRANSMISSION OF HIV ASTHO worked collaboratively with CDC to notify state health agencies of a report in the August 20th issue of *Lancet,* which discussed a possible nocosomial transmission of HIV. The case involved an 11-month boy who had no identified risk for acquisition of HIV. The investigation, led by New York City health department official, Dr. Susan Blank and CDC's Dr. R.J. Simonds, concluded that although the exact mechanism of transmission remains unknown, the most likely opportunity for exposure to blood or body fluids was during medical procedures performed by health care workers treating other children with AIDS. The infant was hospitalized for a bacterial eye infection soon after his birth and did not receive any blood or blood products. The parents and hospital care givers have all tested negative for HIV. Dr. Blank also reports that "there were nor overt breaches of standard infection control," and that hospital employees in contact with the boy had been trained in universal precautions.

COMBINATION TB DRUG APPROVED The FDA has approved the combination drug Rifater for the treatment of tuberculosis. The new combination blends combines three previously approved drugs, and was developed to facilitate administration of therapy. Use of combination drugs has been recommended by the CDC and the World Health Organization (WHO) to decrease the number of patients who do not comply with the standard long-term multidrug regimen for treating TB. The approved formula has been used successfully in Europe, Africa, and Hong Kong since the mid 1980's.

HEMOPHILIAC SETTLEMENT REJECTED The lawsuit that was filed on behalf of more than 10,000 HIV infected hemophiliacs against the National Hemophilia Foundation and four other blood product manufacturers (see the October 1993 *ASTHO HIV/AIDS Update*) resulted in a proposed settlement, subsequently rejected by the plaintiffs. Two medical supply companies, Baxter International and Rhone-Poulenc Rorer, agreed to pay up to $160 million to HIV infected hemophiliacs and their survivors to settle allegations that they sold blood-clotting products tainted with HIV. The National Hemophilia Foundation and the two other defendants did not participate in the settlement filed in a Chicago Federal District Court.

INTERNATIONAL NEWS

10TH INTERNATIONAL CONFERENCE ON AIDS Almost 10,000 people from more than 140 countries attended the Tenth Annual International Conference on AIDS held in Yokohama, Japan. Like previous global AIDS conferences, the Yokohama meeting served as a forum to discuss recent findings in epidemiology and prevention, societal response, education, basic science, clinical science and care. **Dr. George Rutherford, State Health Official of California**, who attended the week long conference, noted the "remarkable success," of the public health STD prevention efforts in Thailand. Rutherford emphasized that scientists are making efforts to expand basic scientific research in order to better understand the virus. He also pointed to the long term survivors of HIV as a promising area of research, (states may be interested in reading Dr. Rutherford's editorial that accompanied a study published in August issue of *The British Medical Journal,* which reports that a significant minority of hemophiliacs infected with HIV may live for up to 25 years before developing symptomatic disease.

United States health officials attending the conference hailed the results of the ACTG 076 trial as a critical success and devoted considerable attention to the topic during the meeting. However, like last year's conference, this year's meeting did not reveal any significant breakthroughs in the fight against HIV. Meeting organizers agreed that future global conferences should be held every other year.

SURVEILLANCE NEWS

SURVEILLANCE REPORT RELEASED The CDC *HIV/AIDS Surveillance Report,* which provides data on reported cases of HIV/AIDS is now available. The document contains information on the number of HIV and AIDS cases reported through December of 1993 and represents 12 months of data. Typically, the surveillance report is published quarterly, however, due to the modifications made to the HIV/AIDS reporting system, the publication of this report was delayed. Unlike previous HIV/AIDS surveillance reports, this latest surveillance report provides data on cases of HIV infection from states that require confidential reporting of HIV. Copies may be obtained by calling the National AIDS Clearinghouse at 1-800-458-5231.

RESEARCH & HEALTH CARE NEWS

PREVENTING HIV TRANSMISSION DURING INVASIVE PROCEDURES CDC researchers, David M. Bell, M.D., Barbara R. Gooch, DMD, MPH, and Craig N. Shapiro, MD, recently published an article which reviews the background of CDC's efforts to address the potential for HIV transmission to patients during invasive procedures. The article appears in the *Journal of Public Health Dentistry* (53:3, 1709-3, 1993) and the *Federal Bulletin* (Vol 81, NO 1, 1994, pp. 35-41). The authors use HBV as a model for understanding modes of HIV transmission and point out that the CDC 1991 recommendations reflect data indicating the risk of HIV transmission in invasive procedures is small, "but that for some invasive procedures standard infection control practices may not be sufficient."

FOR YOUR CALENDAR

September 7-9	***"Assuring Health and Wellness Into the Millennium"*** **1994 ASTHO Annual Meeting** St. Louis, MO.
September 12	**Institute of Medicine Committee to Study HIV Transmission Through Blood Products Public Meeting** Washington, D.C. Contact Kristina Becker (202) 334-2039
September 15-18	**1994 National Congress on HIV/AIDS in Racial/Ethnic Populations** Washington D.C.
September 19-20	**HRSA Meeting: Zidovudine Therapy for Reduction of Perinatal HIV Transmission: Implications for Care** Washington D.C.
September 22	**"Substance Abuse: Clinical Management Issues"** 1:00 p.m. E.S.T. HRSA Clinical Call Series Fax Questions to: Dr. Macher (301) 443-1719
October 11-12	**CDC Advisory Committee on the Prevention of HIV Infection Meeting** Atlanta, GA Contact Connie Granoff (404) 639-2918
October 13	**ASTHO HIV/AIDS Committee Meeting** Atlanta, GA
October 29 - November 1	**1994 National Skills Building Conference** Atlanta, GA Call NMAC at (202) 546-6119 for more information.
October 30 - November 3	**American Public Health Association 122nd Annual Meeting** Washington D.C. Call (202) 789-5646 for information.

RESOURCES

CLEARINGHOUSE DOCUMENT DELIVERY SYSTEM AVAILABLE The National AIDS Clearinghouse has recently established a document delivery system, which makes it possible to receive photocopies of documents directly from the Clearinghouse instead of through publishers. A $5.00 fee is charged for each document up to two pages and five cents is assessed for each additional page. Questions about the document delivery system should be addressed to Clearinghouse Reference Specialists at 1-800-458-5231.

ALL AIDS ISSUE OF JAMA The August 10th issue of the *Journal of the American Medical Association* is devoted entirely to reports of AIDS-related research. Among the studies discussed are the efficacy of zidovudine, the "limited effects of HIV counseling and testing for women," the prevalence of tuberculosis and TB in homeless populations, and HIV seroprevalence among young gay and bisexual men in San Francisco. The issue also contains letters that address a variety of topics, including the possibility of female-to-female transmission of HIV through sexual contact, a case of probable HIV transmission during a "bloody fight," regulating syringe exchange programs, and the potential cost of screening surgeons for HIV.

RYAN WHITE CARE ACT PUBLICATIONS AVAILABLE HRSA has recently developed a resource manual entitled "Determining the Unit Cost of Services." The guide is directed towards State consortia and local planning councils and is intended to provide tools for estimating the average unit cost for services funded by the Ryan White CARE Act. The National Association of Protection and Advocacy systems, Inc., through a contract with HRSA, has released "Cross-Cutting Evaluation of Four HIV/AIDS Legal Advocacy Projects," which discusses SPNS projects that provide advocacy for health and support services. Copies of both these publications may be obtained by contacting Rhonda Hopkins at (301) 443-6560.

COMMUNITY PLANNING TECHNICAL ASSISTANCE The National Association of People with AIDS (NAPWA), through a CDC grant, has produced a manual entitled *Positive Input: Your Guide to HIV Prevention Community Planning*. The guide gives a historical overview of prevention planning, and focuses on the involvement of people living with HIV disease in the prevention planning process. To obtain copies call NAPWA AT (202) 898-0414.

STATE HIV TESTING POLICIES EXPLORED Two recent studies, conducted by researchers at the University of California School of Medicine, and funded in part by the agency for Health Care Policy and Research, examine issues surrounding state HIV testing

policies. The first study examines the relationship of testing policies to previous and voluntary HIV testing. Results indicate that individuals at little or no risk for HIV are not likely to be tested regardless of State policies. Those at highest risk may be more concerned about the psychologicalrepercussions of being tested than about state policies. See the *Journal of Acquired Immune Deficiency Syndromes*, (7(4), pp 403-409) for more information.

The second study published in the *Journal of the American Medical Association* (271 (11), pp. 851-858), examines the cost effectiveness of mandatory testing of doctors and dentists and concludes that "one-time testing of surgeons and dentists, with mandatory restriction of practices of those found to be HIV-positive, is more cost-effective than other policies." The authors however, do underscore the fact that cost effectiveness varies tremendously under different scenarios, and that the ethical, social, and public health implications of mandatory testing should be carefully considered.

CDC AIDS FACT BOOK CDC has released it's *1994 Centers for Disease Control and Prevention HIV/AIDS Fact Book.* This publication contains statistical information on HIV/AIDS and highlights significant prevention accomplishments for calendar year 1993. Additional copies may be obtained by calling (404) 639-0938.

MEDICAID PAYMENT POLICIES RESTRICT AVAILABILITY OF AIDS MEDICINES A recent study published in the April 1994 issue of *The Annals of Pharmacotherapy* surveyed State affiliates of the American Pharmaceutical Association (APhA) to determine which services pharmacies are providing to Medicaid patients infected with HIV or tuberculosis. "Almost half of the pharmacies reported that Medicaid payment levels for prescription drugs in their States exert moderate disincentives to provide HIV-related drugs to Medicaid patients." The authors conclude that the high inventory costs of these expensive drugs combined with low Medicaid dispensing fees, "discourage pharmacies from stocking and dispensing the medications." The authors also conclude that the restrictive policies "may cost Medicaid more in the long run, since they ultimately result in noncompliance with treatment recommendations that may lead to worsening of disease or hospitalization for extensive care." The article also calls for national standards for determining Medicaid policies for HIV and AIDS-related drug therapies. See Pages 528-535 for details.

PREVENTION MESSAGE FOR AFRICAN AMERICAN FEMALES The National Urban League's National AIDS Minority Information and Education Project has released a prevention education pamphlet, entitled "4 Sisters Only." The publication is targeted to African American females between the ages of 18-24 and provides HIV/AIDS prevention information as well as serving as an "empowerment piece, encouraging women to discuss sexuality issues." Copies may be obtained by contacting Sharon Mottley at (212) 310-9232.

ASTHO NEWS

SEEMA VERMA PROMOTED TO HIV/AIDS PROJECT DIRECTOR Seema Verma, HIV/AIDS Project Coordinator, has been promoted to the position of HIV/AIDS Project Director. Margaret Skelley, who previously directed ASTHO's AIDS efforts has been promoted to the position of Director of Public Health Programs. Ms. Skelley will continue to provide guidance to the AIDS project and foster improved communications and linkage among ASTHO's AIDS efforts and those of the School Health, MCH and Immunization projects.

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The Association of State and Territorial Health Officials (ASTHO) represents the chief public health officers in each of the 50 states, the District of Columbia and the U.S. Territories and Possessions. ASTHO addresses the range of public health issues, including HIV/AIDS

*The **ASTHO HIV/AIDS UPDATE** is designed to facilitate communication among states on HIV/AIDS issues, and is made possible through a cooperative agreement with the Centers for Disease Control and Prevention. Please send information on your state's efforts which might benefit other states in addressing HIV/AIDS issues to:*

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TESTIMONY ON HOME SAMPLE COLLECTION KITS FOR HIV TESTING

PRESENTED BY

MARGARET SKELLEY
DIRECTOR OF PUBLIC HEALTH PROGRAMS

ON BEHALF OF

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
COUNCIL OF STATE AND TERRITORIAL EPIDEMIOLOGISTS
NATIONAL ALLIANCE OF STATE AND TERRITORIAL AIDS DIRECTORS
ASSOCIATION OF STATE AND TERRITORIAL PUBLIC HEALTH LABORATORY DIRECTORS

TO

THE FOOD AND DRUG ADMINISTRATION BLOOD PRODUCTS ADVISORY COMMITTEE

JUNE 22, 1994

Testimony to FDA Blood Products Advisory Committee
ASTHO, ASTPHLD, CSTE, NASTAD
June 22, 1994

Good morning. I am Margaret Skelley, Director of Public Health Programs with the Association of State and Territorial Health Officials (ASTHO), which represents the chief health officers from each of the 50 states, the District of Columbia, and the U.S. territories. The testimony I will be delivering reflects a concerted effort of ASTHO and several of its affiliate organizations: the Council of State and Territorial Epidemiologists (CSTE), the National Alliance of State and Territorial AIDS Directors (NASTAD), and the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD). ASTHO and its affiliates have been actively engaged in examining the issues surrounding home collection kits and those related to the home HIV testing kits that were under FDA consideration previously. State Health Agency activity on this issue accelerated in January of this year in response to the heightened media attention received by the kits. At that time, ASTHO and its affiliates wrote to FDA urging the agency to fully consider potential public health implications of this technology prior to making any decision regarding approval or marketing of the kits. In March of this year, the ASTHO HIV/AIDS committee met with representatives of the Centers for Disease Control and Prevention and the FDA and heard presentations from two of the manufacturers of home sample collection kits. Since then, state health department representatives have worked collaboratively to respond to FDA's request to identify the potential benefits and losses of home collection kits from a public health standpoint, which I will share with you today.

Before I begin, I will provide some brief background on the current system of HIV counseling and testing. The Centers for Disease Control and Prevention (CDC) has recommended, and state health departments have supported, the provision of high quality face-to-face counseling both before and after testing for HIV infection to educate individuals receiving testing on HIV and the testing process. Counseling provides critical opportunities to promote understanding of transmission, assess risks and offer information on risk reduction strategies. For those testing positive, such interactions also provide a forum for individuals to learn about the clinical care necessary to delay disease progression, and to receive needed services or referrals for them. State health agencies also rely on counseling sessions to offer voluntary partner notification services whereby sexual or drug-using contacts on the person testing positive are notified of possible exposure to HIV and are provided similar counseling and testing services.

CDC has also recommended that states make HIV infection a reportable condition. As outlined in a recently formulated position on home sample collection for HIV testing developed by the Council of State and Territorial Epidemiologists, "many states provide follow-up counseling, clinical and support services, and partner notification services for each individual reported with HIV infection. These activities focus on promoting the well-being of the infected person and on preventing transmission through targeted risk reduction follow-up and outreach. These activities are consistent with the traditional responsibility of public health authorities to assure health care and to protect the public from communicable diseases."

ASTHO and its affiliates believe it is important to consider home collection kits for HIV testing in the context of the current system of HIV prevention. We urge the FDA and the Blood Products Advisory Committee to carefully consider the impact of home sample collection kits on public health activities in the approval process.

POTENTIAL BENEFITS OF HIV HOME COLLECTION KITS

State health agencies recognize that home collection kits may offer an important contribution to the current system of HIV prevention for the following key reasons:

- The kits would likely facilitate access to HIV testing, particularly for persons residing in medically underserved areas. More importantly, the kits may encourage persons who may not otherwise seek testing to discover their serostatus, thus reducing HIV transmission. Furthermore, the marketing and advertising of home collection devices may increase public awareness of HIV.

- Scarce public resources would likely be made more readily available to provide face-to-face counseling for those in greatest need, who may not avail themselves to private, home collection kits. Additionally, the availability of home collection kits will likely reduce waiting lists and backlogs for public testing sites, by reducing the number of repeat testers or the "worried well."

- Finally, individuals may be tested earlier in the course of the disease and may potentially enter systems of care sooner. If persons do enter systems of care earlier, then despite the anonymity of the home sample test, surveillance efforts in states that require providers to report HIV infection by name may actually be strengthened. Thus, home collection kits may work to enhance public health's early intervention and surveillance efforts.

POTENTIAL LOSSES OF HOME COLLECTION KITS

Counterbalancing these potential benefits are several significant potential losses. These can be categorized into impeding public health activities, the feasibility of providing quality counseling, accessibility of the test kits and the home testing methodology.

- ASTHO and its affiliates recognize the potential of home collection kits to impede public health activities. Absent strong linkages to public health and health care delivery systems, persons being tested via home sample collection may not adequately access needed preventive, early intervention and treatment services. Furthermore, the current HIV prevention efforts via partner notification may be diminished. In addition, the capacity to conduct laboratory-based HIV and AIDS surveillance by name or code may be hindered or lost, thereby increasing the reliance on health care providers for HIV/AIDS surveillance.

■ State health departments also question the feasibility of providing the quality counseling CDC has recommended, via the telephone, as would be necessitated by home sample collection kits. This is a particularly critical issue for persons testing HIV positive. Telephone post-test counseling may be less effective than that offered in a face to face, interactive setting. The inability of telephone counselors to fully assess client acceptance of positive test results may also increase the likelihood of adverse events such as increased suicide rates. Likewise, the possible inability of consumers to fully accept positive test results via telephone may potentially result in an increase in, or a return to, risky behavior due to denial. Those newly diagnosed with HIV, in particular, may suffer from the lack of opportunities for enhanced, multi-session counseling afforded by home sample methodologies.

■ Cost may be a barrier to low income, high risk populations most in need of knowing their serostatus and changing behavior.

■ States are concerned about the availability of the home collection kits to minors, who may be among the least prepared to accept positive test results.

■ Blood sample integrity may be compromised if samples are collected or transported inappropriately (i.e. in plastic bags), thus requiring repeat testing and potential loss of clients to needed counseling and care.

■ Liability for false positive or false negative results, accidental exposure, or unintended use of the products, may be too great a burden for laboratories or industry to assume. This may be more of an issue for industry or laboratories.

■ Persons using home collection kits are not likely to have been trained in universal precautions and improper collection, disposal and shipment could pose a risk to others. Improper lancet disposal occurring in even a fraction of consumers using the product could, at a minimum, result in increased fear of HIV transmission, or even in actual transmission among those coming in contact with the lancet.

■ Lack of understanding regarding mail transportation of potentially infected blood samples may result in increased public fears and discrimination.

State health departments also share the concerns regarding the quality of specimen collection and specimen rejection criteria that will be/were expressed by my colleague Dr. Carpenter from the Association of State and Territorial Public Health Laboratory Directors.

ASTHO, CSTE, NASTAD, ASTPHLD
POSITION HOME SAMPLE COLLECTION FOR HIV TESTING

Before I discuss the ASTHO, CSTE, NASTAD, ASTPHLD position on home collection kits, it is important to note that the potential benefits of home sample collection kits coupled with the potentially serious implications these kits could have on the existing system of HIV prevention, has generated a lively debate within the public health community. The position which I am about to share with you reflects not a consensus of every state in the union, but a considered compromise between states that strongly support home collection kits and those which ardently oppose it.

ASTHO and its affiliates, CSTE, NASTAD, and ASTPHLD recommend that HIV testing ideally be done in settings where appropriate pre and post test counseling can be provided by skilled and knowledgeable counselors who are able to refer uninfected high risk and infected persons to appropriate follow-up services available locally including risk reduction interventions, clinical follow-up, and partner notification services.

States recommend that FDA license home collection kits for HIV testing only under the following conditions:

Appropriate standards, safeguards, and evaluation procedures should be formulated by FDA, in collaboration with CDC and states, for the laboratory testing of home collection samples, counseling procedures, and referral and follow up services. Manufacturers must be required to establish quality assurance mechanisms to ensure adherence to these standards. Additionally, manufacturers should be required to perform studies to evaluate the impact of HIV home collection kits on the system of HIV prevention.

Manufacturers should be obligated to routinely provide surveillance and demographic information to state and local health departments in accordance with state laws and to work collaboratively with public health agencies to develop strategies to assure that HIV positive and high risk seronegative clients, in particular, receive the necessary follow up.

Manufacturers should be required to conduct a confirmatory test on a repeatedly reactive sample prior to <u>any</u> post-test message being given to the consumer.

Home collection devices should be marketed only in jurisdictions where such marketing is consistent with state and local HIV reporting, and informed consent laws, counseling standards and other relevant public health statutes.

States believe that home sample collection kits hold significant potential for increasing consumers' knowledge of their serostatus; states look forward to participating constructively in making this potential a reality. On behalf of ASTHO, CSTE, NASTAD, and ASTPHLD, I thank you for the opportunity to comment and welcome any questions you may have.