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File
Agencies - HHS -
Coordinating Group

TO: MEMBERS, HHS COORDINATING GROUP ON HIV/AIDS

FROM: Director, Office of HIV/AIDS Policy
OSOPHS, DHHS

SUBJECT: Update of the Public Health Priorities Associated with Protease Inhibitors

In February 1996, the Department began its assessment of the impact of protease inhibitor therapy on Public Health Service programs. By April 1996, our Office and the Operating Divisions had identified and developed plans for addressing 10 priorities. Attachment I contains the list of Department priorites with specification of leads and participating Operating Divisions. Highlights of the accomplishments achieved from November 1995 through October 1996 include the following:

- FDA approval of 3 protease inhibitors;
- CDC publication of provisional recommendations for post-exposure prophylaxis for health care workers;
- HCFA letter to State Medicaid Directors;
- HRSA obtained increases in ADAP for Ryan White Title II; and
- Clinical Conference call on combination therapy.

The cornerstone of Department efforts during Winter 1996 through Fall 1997 has been involvement in the development and approval of principles (led by OAR, NIH) and guidelines (convened by our Office with the Henry J. Kaiser Family Foundation with NIAID, NIH as the lead Operating Division) in partnership with academia, scientists, and health professional and consumer clinical experts.

In addition, excellent accomplishments have been made regarding the remaining protease inhibitor priorities. We would like to you to provide us with a summary of the progress made during the past year. We will discuss these summaries and Department responsibilities regarding implementation of the guidelines for the use of antiretroviral agents at our October 1997 HHS Coordinators meeting. Please send your summaries **no later than Monday, October 20** to Elaine M. Daniels, M.D., Ph.D. or phone her at 202-690-5560 if you have any questions or wish to discuss the content of your summary.

I look forward to seeing you later this month.

Eric P. Goosby, M.D.

cc: Dr. Eisenberg
Dr. Clinton

File

Attachment I

Protease Inhibitors: DHHS Public Health Priorities

1. **Rapidly disseminate accurate information** to providers and consumers about the current status of the inclusion of protease inhibitors in antiretroviral therapy. **Lead**: HHS Coordination Work Group

2. **Identify the costs of combination therapy** that include protease inhibitors, viral load testing and barriers to providing funding.
Lead: HRSA

3. **Conduct a state of the art conference. Lead**: OAR, NIH

4. **Develop and implement the research agenda** associated with combination antiretroviral therapy that includes protease inhibitors.
Leads: NIAID, NIH; CDC

5. **Educate and train health care professionals**: 1) provide updates on protease inhibitors; and 2) develop the HHS training plan.
Lead: HHS Coordination Work Group (HRSA's AETC Program)

6. **Ensure access** to protease inhibitors for individuals served by Federal programs. **Leads**: HRSA and HCFA

7. **Establish prevention guidelines** on the use of protease inhibitors (lead: CDC). These guidelines should include a specific focus on health care workers. **Lead**: CDC

8. **Provide regulatory updates. Lead**: FDA

9. **Establish clinical practices (guidelines)** on the use of protease inhibitors.
Leads: OHAP and NIAID, NIH

10. **Evaluate the impact** of the use protease inhibitors. **Leads**: AHCPR, HRSA, and HCFA

Attachment I
Protease Inhibitors: DHHS Public Health Priorities
Participating Operating Divisions

Priority	HHS Operating Division/Agency

	CDC	NIH	HRSA	SAMHSA	IHS	FDA	HCFA	AHCPR	ACF
1*									
2			●	●	●		●		●
3	●	●	●	●	●	●	●	●	●
4	●	●	●	●		●	●	●	
5*									
6	●		●	●	●		●		●
7	●								
8						●			
9	●	●	●	●	●	●	●	●	●
10			●	●	●		●	●	●

* Priorities 1 and 5 will be addressed by the HHS Coordination Work Group (convened by OHAP with members from relevant Operating Divisions)

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

HHS COORDINATING COMMITTEE ON HIV/AIDS

September 25, 1997, 2:00 - 4:00 pm

AGENDA

I.	New Role of OHAP Office	Dr. Clinton Dr. Goosby
II.	HIV/AIDS PHS Retreat	Dr. Goosby
III.	Demonstration Project	Dr. Goosby Dr. Martin

IV. Updates

1. Vaccine Initiative - NIH
2. Guidelines for Antiretroviral Therapy - Pediatric, Adolescent/Adult, Perinatal

* Monthly meetings of the Coordinating Committee on HIV/AIDS will take place on the 4th Thursday from 2 - 4 pm

OHAP/OSOPHS September 24, 1997
Elaine M. Daniels, MD, PhD

1997 HIV-RELATED GUIDELINES AND RECOMMENDATIONS

ANTIRETROVIRAL THERAPY

- *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents*

  Report of the NIH Panel to Define Principles of Therapy of HIV Infection

  Status: Draft Federal Register public comment period closed on July 21, 1997. More than 8,000 people received the guidelines document (>6,000 people received the text on-line, and > 2,000 people were sent copies of the documents). The ~ 300 comments have been addressed and the final draft will undergo final review by the DHHS/Kaiser Panel in October 1997.

- *U.S. Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs During Pregnancy for Maternal Health and Reduction of Perinatal Transmission of Human Immunodeficiency Virus Type I*
  Status: Final Draft. Federal Register 30-day comment period closed August 4, 1997. Final PHS Agency clearance to be obtained by end September 1997. Publication in the **MMWR** by the end of 1997.

- *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection*
  Status: Draft. Federal Register publication September 29, 1997 for 30-day public comment period.

OTHER

- *The 1997 USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus*
  Status: Final **Publication: MMWR,** June 27, 1997, vol. **46**/ No.RR-12

- *The 1997 Revised Guidelines for the the Performance of CD4+ T Cells: Determinations in Persons Infected with HIV*
  Status: Final **Publication: MMWR,** January 10, 1997, vol. **46** / No. RR-2

- *Update: Provisional Public Health Service Recommendation for Chemoprophylaxis After Occupational Exposure to HIV.* **MMWR,** June 7, 1996, vol. **45**/ No. 22
  Status: Interagency Working Group met during late Spring-Summer 1997. Final recommendations available by Fall 1997.

- Recommendations for Chemoprophylaxis After NonOccupational Exposure to HIV
  Status: Under consideration/development. Interagency Working Group meeting July 23-25, 1997.

To access these documents, contact

ATIS
The HIV/AIDS Treatment Information Service
P.O. Box 6303
Rockville, MD 20849-6303

Tel. 1-800-448-0440

Web Site- www.HIVATIS.org

OR

THE CDC NATIONAL AIDS CLEARINGHOUSE

Tel. 404-982-0353 or Fax. 404--982-0346 or Web Site- www.cdcnac.org\.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Substance Abuse and Mental
Health Services Administration
Rockville MD 20857

Dear Colleague:

It is with great pleasure that I forward to you a copy of *Producing Results*, the 1998 Report to the Nation, developed by the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration. Like its predecessor produced in 1995, this document describes the measures taken by CSAT and the initiatives it has funded to reduce the health and social costs of alcohol and drug use, including increasing public safety by reducing drug-related crime and violence. Beyond these descriptions, however, this report celebrates the progress that our field has achieved, made possible only through the cooperative efforts of Federal, State and local partners. It also points to the increase in positive health outcomes achieved through interagency collaboration at the community level.

From this report, you will learn of the many ways that CSAT has successfully collaborated with State and Federal courts and social service entities to:

- promote a comprehensive continuum of care and effective partnerships among criminal justice agencies and community treatment and recovery service providers;
- lower the incidence of HIV, TB, hepatitis, and other infectious diseases transmitted sexually or by intravenous drug use through outreach and intervention to bring at-risk populations into treatment;
- develop effective, gender-specific residential and outpatient treatment services for pregnant and parenting women and their children;
- assist the States to adapt to the managed care environment while providing top-quality public alcohol and substance abuse treatment services;
- monitor treatment outcomes through scientific evaluation to determine what treatment approaches work best for which clients;
- assess treatment needs by geographical region, drugs of abuse, and client populations so as to allocate resources where they are needed and identify service gaps;

- establish clinical standards for treatment, encourage innovative treatment approaches for hard-to-reach populations, and obtain, develop and apply knowledge to improve services and service delivery; and

- disseminate knowledge and communicate to the field through meetings, publications, and the Internet.

Thank you for your efforts on behalf of those facing problems of substance abuse. I trust that our collaboration will continue to produce positive results.

Sincerely,

Camille T. Barry, R.N., Ph.D.
Acting Director
Center for Substance Abuse Treatment

Enclosure

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Center for Substance Abuse Treatment

Producing Results

. . . a report to the Nation

1998

SAMHSA