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001. memo	David Harvey to Paul Yandura re: Biography for AIDS event (Personal) (1 page)	11/14/1997	b(6)

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Clinton Presidential Records
National AIDS Policy Office

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

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

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AIDS Policy Center
For Children, Youth & Families

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Suite 201
Washington, DC 20006
Tel. (202) 785-3564
Fax (202) 785-3579
E-mail APCCYF@aol.com

November 4, 1997

Ms. Sandra Thurman
Mr. Paul Yandura
Office of National AIDS Policy
The White House
808 17th Street, NW
Washington, DC 20006

Dear Sandy and Paul:

Thank you for following up on my letter to the President yesterday concerning World AIDS Day, 1997. In response to your questions, Paul, I recommend the following:

Local Contact

In addition to the Philadelphia and Baltimore pediatric AIDS programs, AIDS Policy Center has several local affiliate pediatric AIDS programs. I would highly recommend that if the President wants to make a visit to a local program, that he consider the following:

> CHIPS for Families Program
> Children's National Medical Center
> Special Immunology Services
> 111 Michigan Avenue, NW
> Washington, DC 20010
> Contact: Bret Loeschelt, M.D., 202-884-3495

This program receives support from every title of the Ryan White CARE Act, and is a major component of the local CARE Act Title IV program for children and families living with HIV and AIDS. Dr. Loeschelt can also be a resource for locating children and families living with HIV and AIDS who can participate in the State Department and Justice Department events.

First Lady's Column

Hillary Clinton played a role in helping to secure the new proposed FDA rule that will require pharmaceutical companies to test new drugs in children – including children with AIDS. Mrs. Clinton could easily

write a column on the new proposed rule and the role that it can play in helping to secure access to new AIDS drugs for children. I attach additional background information on this issue.

General Barry McCaffrey

Although advance work would need to be done in order to secure a welcoming environment for General McCaffrey to visit a pediatric/family AIDS program, I would recommend that he visit our affiliate women and children's HIV program at the University of Miami in Miami, FL. The incidence of HIV infections related to IV drug use and crack cocaine are well documented, and General McCaffrey may wish to visit with families living with HIV who are in recovery. Otherwise, I would recommend that General McCaffrey issue a statement in support of drug treatment on demand (and needle exchange) as a way of reducing perinatal HIV transmission and the number of children living with HIV and AIDS throughout the United States.

Proclamation

We would welcome a proclamation by the President that recognizes the treatment and research advances that have been made in pediatric AIDS that is extending quality of life, with an acknowledgment that the private and public sectors must work closely to make these treatment advances available in developing countries. The proclamation should also acknowledge that public investment in AIDS prevention, research, care and housing is paying off for children and families living with HIV and AIDS. I would also recommend that specifically, Title IV of the Ryan White CARE Act be acknowledged as an important source of health care access for children with AIDS in the United States. I attach a fact sheet for additional background information.

Paul, at your suggestion, I have contacted the State and Justice Department point persons for World AIDS Day and am working to locate children and families to participate in the events. As the sole national pediatric AIDS group in Washington, I am very hopeful that representatives of AIDS Policy Center will be included in any event the President holds, as well as the department events.

I look forward to speaking with you during the next several days. Thank you.

Sincerely,

David C. Harvey
Executive Director

Children's National Medical Center

Serving Children and Their Families Since 1870

111 Michigan Avenue, N.W.
Washington, D.C. 20010-2970
(202) 884-5000

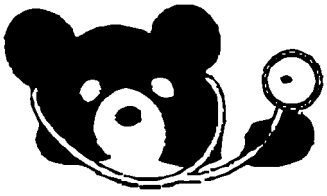
Special Immunology and Burgess Clinic Services

The Special Immunology and Burgess Clinic Services at Children's National Medical Center (CNMC) were developed in the 1980's in response to a growing number of HIV seropositive children and adolescents who sought care at CNMC. Today, CNMC emerges as the premier provider of care for children and adolescents with HIV in the Washington metropolitan area. The Special Immunology and Burgess multidisciplinary teams provide comprehensive HIV-related medical, social and supports services to nearly 400 seropositive infants, children and adolescents of whom 254 have known HIV disease. For infants and children this represent 65% of all "at risk" or infected and 77% of infected children known to be receiving care in the metropolitan area. These multidisciplinary teams consist of subspecialty-trained attending physicians, nurse practitioners, clinic and research nurses, MSW-level medical social work/case managers, psychologists and nutritionists.

Children's National Medical Center is the site of the Washington DC Regional Pediatric AIDS Clinical Trials Unit (ACTU) which offers an array of AIDS Clinical Trials Group (ACTG)-sponsored trials to children and adolescents. These include trials in primary therapy, opportunistic infections, vaccines, and long-term outcomes. Washington Hospital Center is a subsite of the ACTU at CNMC which offers ACTG-sponsored clinical trials aimed at reduction of perinatal transmission of HIV from pregnant women to their infants. Currently over 90 children, adolescents and pregnant women are enrolled in over 16 clinical trials through this ACTU.

Project CHAMP (Children's HIV/AIDS Model Program) at Children's National Medical Center is dedicated to enriching the lives of HIV-affected children, adolescents and their families through education and outreach. Presently, CHAMP operates a network of buddies that provide support services and respite to over 170 HIV infected children and their families, both at home and within the hospital. Additionally, staff are leaders in the development of educational material (including six publications) and programs, targeting families, professional and community-based caregivers. For the past ten years, Project CHAMP has received support from private and public as well as received recognition for its community educational model that includes: two tested training curriculums; collaboration with the private and public sector; and trainings on multiple levels including Training-of-Trainer.

Recently, Children's National Medical Center and the adjacent Washington Hospital Center collaborated to form the Robert H. Parrott Family HIV Clinic. It became



apparent that families, with multiple infected individuals, represent a growing population of individuals affected by HIV in the Washington metropolitan area. The Robert H. Parrott Family Clinic, founded in June of 1996, builds on the growing relationship between the two institutions and provides increased access to care for families. The Robert H. Parrott Family Clinic utilizes the proximity and previously established cooperation between Pediatrics, Obstetrics & Gynecology, and Adult services. It offers coordination of services to adult caregivers and their children infected with HIV. The Parrott Clinic acknowledges the fact that many of the parents of children served by the SIS at CNMC did not receive medical care for themselves, or risked not remaining in care. The individual services of Special Immunology (pediatrics) and The Burgess Clinic (adolescents) at CNMC and Infectious Disease (adults) and Obstetrics/Gynecology (adult & adolescent) at WIIC together formed The Parrott Clinic to provide coordinated services to families.

The mission of CNMC and The Parrott Clinic is care, advocacy, research and education. Compassionate, culturally-sensitive, and ethical care for clients with HIV is paramount. Advocacy for families infected with HIV is a priority as families, burdened with rigorous schedules and responsibilities, do not and cannot get their voices heard. Research is critical to advance treatment for persons with HIV. Research has provided a ray of hope for clients infected with HIV. Education is critical for clients and the community. Clients cannot participate in treatment decisions without clear understanding of the disease process and the impact that treatments may have on this process. The stigma associated with HIV will never diminish unless larger segments of society are educated about HIV.

Special Immunology receives funding through Ryan White Titles I, Title II, Title IV, and Title IV and is a new applicant through Ryan White Title III (application pending).

For further information, please contact:
Brett J. Loechelt, M.D.
Attending Physician, Children's National Medical Center
Assistant Professor of Pediatrics, The George Washington University School of Medicine
Director, The Robert H. Parrott Family HIV Clinic

AIDS POLICY CENTER | **For Children, Youth, and Families** **NEWS**

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FDA ISSUES NEW RULE TO REQUIRE TESTING OF DRUGS IN KIDS

August 13, 1997

At a White House ceremony that was held today, a proposed FDA rule was unveiled that will require pharmaceutical companies to test new drugs in children before or soon after approval for use in adults -- including new AIDS drugs. The rule will become effective after a 90-day comment period.

While AIDS Policy Center is hopeful that the proposed rule will increase the safe availability of new AIDS drugs for children, there are aspects to the rule that are not clear. In addition, the rule does not address pregnant women, an additional area of concern to AIDS Policy Center.

Background

In 1994, the FDA took steps to require pharmaceutical companies to survey their existing adult drug test data to develop guidelines for use of new drugs in children. The rule was widely regarded as not effective, because the course of diseases in children is often different than adults, and the safety of new drugs in children could often not be established using adult data.

Recent information indicated that only 20% of all drugs on the market in the United States have been tested in children, a figure that has dropped over recent years. Of 11 new AIDS drugs, only 5 are approved for children with HIV and AIDS. This has forced many physicians to prescribe the new AIDS drugs for children on an "off label" basis, raising safety questions.

AIDS Policy Center worked to call attention to this issue in coalition with other national children's groups and the Pediatric AIDS Foundation. AIDS Policy Center has testified before the FDA, briefed Vice-President Gore's staff, and conducted a plenary session on the topic at its annual conference in June.

The Pharmaceutical Research and Manufacturers Association (PHARMA) is expected to oppose the rule, but the implications for the proposed FDA rule are unclear.

Proposed FDA Rule

The rule requires a manufacturer of a new drug or new biological product, to submit data before approval or shortly thereafter, safety and effectiveness data for children under the age of 13. The requirement would be waived if: (1) the product has no therapeutic benefit for children over existing treatments or is unlikely to be used in a "substantial number"; (2) studies on the product are impossible or impractical; (3) the product is likely to be unsafe or ineffective in children; and (4) reasonable efforts to develop a pediatric formulation have failed. The proposed rule also requires manufacturers of already marketed drugs and biological products to conduct studies for use in children.

Look for an APC policy brief this fall on this topic once the rule has been finalized and approved by the FDA.

AIDS POLICY CENTER | **For Children, Youth, and Families** **NEWS**

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APC PARTICIPATES IN FDA HEARING ON TESTING OF NEW PEDIATRIC DRUGS

October 28, 1997

The Food and Drug Administration (FDA) convened a public meeting yesterday to hear testimony on a proposed rule that would require pharmaceutical companies to test new drugs – including pediatric AIDS drugs – in children. The FDA unveiled the proposed rule during a White House ceremony last August that AIDS Policy Center attended. The proposed rule was published in the Federal Register to allow for a public commentary period which will close on November 13, 1997.

Currently, it is estimated that 95% of all prescription drugs are prescribed for children on an "off label" basis because they have not been tested in children. Of 13 approved AIDS drugs for adults and adolescents, only 5 of the drugs are approved for children under 13. AIDS Policy Center has worked closely with Vice President Gore's office to call attention to the lack of testing of new AIDS drugs in children, and continues to closely monitor the proposed FDA rule.

Discussion at the hearing focused on drug testing and the approval process, the feasibility of conducting pediatric trials, legal and economic issues, and why the pharmaceutical industry is reluctant to test new drugs in children.

Proposed FDA Rule Waivers

The rule requires a manufacturer of a new drug or new biological product to submit data before approval or shortly thereafter on the safety and effectiveness for children under the age of 13. The requirement could be waived by the FDA if it can be shown that the product: (1) has no therapeutic benefit for children over existing treatments; (2) is unlikely to be used in a "substantial number"(100,000 or more prescriptions or uses); (3) studies on the product are impossible or impractical; (4) the product is likely to be unsafe or ineffective in children; and (5) reasonable efforts to develop a pediatric formulation have failed. The proposed rule also requires manufacturers of already marketed drugs and biological products to conduct studies for use in children.

APC Remarks

AIDS Policy Center delivered remarks before the FDA on behalf of children and families about the importance of testing of new pediatric AIDS drugs, developing pediatric formulations, and the need to access new drugs. APC requested that the FDA take the following action in relation to the proposed rule:

- Enact the FDA rule, but review its implementation after one year by a diverse panel of experts.
- Regard pediatric formulations as a public health safety issue, since families and adults with AIDS face enormous pressures to provide access to new drugs for their children, even if not prescribed.
- Amend the waiver mechanism to tighten and clarify the criteria, including the removal of any reference to 100,000 as a marker for "substantial number." An alternative model for defining substantial number could be the HRSA CARE Act Title IV criteria for evaluating whether Title IV projects have enrolled a "significant number" of patients in clinical research programs.

APC will be submitting written recommendations to the Food and Drug Administration within the next two weeks.

We've Heard

At Saturday night's annual fundraiser for **Children Affected by AIDS Foundation** in Los Angeles, a one-of-a-kind barbie doll of **Demi Moore** was auctioned for $20,000!.....Congratulations to Title IV projects who competed successfully in the Foundation's latest RFP process....Over 50 people have registered for **APC's HRSA/NPHRC Title IV** pre-institute conference training on Medicaid managed care...hurry and register before November 10....we promise to make it fun!

Be Sure to Mark Your Calendar!

VOICES '98
New Hope, New Options, New Needs

The annual conference of the AIDS Policy Center for Children, Youth & Families will be held on
May 16-19, 1998
at the
Hyatt Regency - Capitol Hill, Washington, D.C.

We will update you with registration information at a later date.

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AIDS
Policy Center
For Children, Youth & Families

Facts About AIDS In Children, Youth and Families

Memorandum

October 1997

- AIDS is the second leading cause of death among Americans between the ages of 25 and 44. More than 600,000 Americans have been diagnosed with AIDS, and sadly, more than 375,000 of them have already died.

- The Centers for Disease Control and Prevention (CDC) estimates that between 40,000 and 60,000 Americans are becoming newly infected each year. They also estimate that between 650,000 and one million people are currently living with HIV.

- The expanding face of the AIDS epidemic is becoming increasingly young. Best estimates are that one-quarter of all new HIV infections occur between the ages of 13 and 21. This means that two Americans under the age of 21 become infected every hour of every day.

- Over 7500 children under the age of 13 have been diagnosed with AIDS. Vertical transmission—transmission of HIV from mother to child—accounted for 89% of AIDS cases diagnosed in 1996 in children under thirteen years of age.

- Women are the fastest growing group among people diagnosed with AIDS. The CDC recently reported a 63% increase in women living with AIDS between 1991–1995. They now comprise almost 20% of the total number of AIDS cases in the U.S. A great majority of these women are of childbearing age, and if the epidemic continues at its current pace, as many as 80,000 children will be orphaned by the year 2000.

- More women and children are living with AIDS than ever before. The estimated number of women, infants, and children living with AIDS from July, 1986 to June, 1996 is 33,550. From July, 1987 to June, 1997, this number rose to 43, 092. That is a difference of 9,542 and an increase of 28.44 percent.

- Racial and ethnic minorities have been disproportionately affected by the AIDS epidemic. African Americans, who represent approximately 12% of the U.S. population, account for 42% of newly reported AIDS cases in 1996. Hispanics, who also account for 12% of the U.S. population, represent 19% of new AIDS cases. In 1996, African Americans and Hispanics comprised 53% of cumulative AIDS cases. For African American women aged 25-44, AIDS is the leading cause of death.

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- The CDC reported a 19% decrease in AIDS deaths in the first nine months of 1996. However the decrease of death rate for women was just 7%, compared to 22% in men. The death rate dropped 28% for whites, but only 10% for African Americans and 16% for Hispanics.

- Title IV of the Ryan White CARE Act is a key funding source for HIV/AIDS services for children, youth and families. Title IV funds 338 sites in 26 states, the District of Columbia and Puerto Rico, and reaches approximately 50.000 children, youth, women and families living with or effected by HIV/AIDS.

- Of 14 approved AIDS drugs for adults and adolescents, only 5 are approved for children. There is a critical shortage of prescription drugs that have been tested and labeled for use in children. As a result, many pediatricians prescribe medications without the guidance of scientific research, often referred to as "off label" prescribing of drugs.

- Exciting new treatments are available for people living with HIV and AIDS. In light of these important advances and the recently release statistics, it is now more important than ever that women, children, youths, and families have access to comprehensive health care.

This fact sheet of AIDS Policy Center is made possible through the generous donation of individual, professional, consumer and organization member dues. Write or email us about additional benefits of APC membership.

AIDS Policy Center
For Children, Youth & Families

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10-4-97 — 4pm EST Harvey

November 3, 1997

The President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20008

Dear Mr. President:

The theme of this year's World AIDS Day, scheduled for December 1, 1997, is "Give Children Hope in a World with AIDS." While we have much to be hopeful for, the pediatric AIDS epidemic continues in the United States and globally with 1,000 new HIV infections in children each day.

As the only national pediatric AIDS group in Washington focused on care, prevention and research for children and families living with HIV and AIDS, I am writing to offer assistance in locating an appropriate pediatric and family AIDS program near Washington for you to visit on World AIDS Day.

Over 350 affiliate members of AIDS Policy Center located in 28 states, DC, and Puerto Rico provide services to 35,000 infected and affected children, youth and parents living with HIV and AIDS. On December 1, a visit by you to one of our programs near Washington would help to educate the world about the latest research, care and prevention advances for children and families who live with HIV and AIDS every day.

Mr. President, for your information, I attach a description of The Circle of Care, a program serving children, youth, woman and families living with HIV and AIDS in the Philadelphia metropolitan area. The program is administered by the Family Planning Council of South-Eastern Pennsylvania. I feel that with the program's excellent reputation and proximity to Washington, it provides a very good opportunity for you to further demonstrate your personal commitment to fighting AIDS.

I look forward to working with your staff on confirming arrangements for your participation in World AIDS Day events on December 1, 1997. Thank you for considering this request.

Sincerely,

David C. Harvey
Executive Director

THE CIRCLE OF CARE
CLINICAL SITES

The Children's Hospital of Philadelphia
34th & Civic Center Boulevard
Philadelphia, Pennsylvania 19104
Contact: James Vagnoni,
Coordinator of Special Immunology Program
(215) 590-4990

St. Christopher's Hospital for Children
Front Street & Erie Avenue
Philadelphia, Pennsylvania 19134
Contact: Carole Treston, R.N.
HIV Program Coordinator
(215) 427-5284

Care Plus Clinic
at Strawberry Mansion Health Center
2840 W. Dauphin Street
Philadelphia, Pennsylvania 19132
Contact: Letitia O'Kicik, M.D.
Clinical Director
(215) 685-2421

Mayor: Edward G. Rendell

Congressman: Thomas M. Foglietta

Senator: Arlen Specter

For Further Info
Contact: Alicia Beatty, Director
(215) 985-2657

260 South Broad Street
Suite 1000
Philadelphia, PA 19102

The Circle of Care

The Circle of Care, a project of the Family Planning Council, was founded in 1989 as a Pediatric AIDS Services Demonstration Project. It is the only Ryan White Title IV funded program in Pennsylvania. The Circle has provided services to over 900 families since 1989.The purpose of the Circle is two-fold: 1) to provide comprehensive, family-centered care to HIV infected and affected families; 2) and to prevent the spread of HIV through targeted community-based outreach, prevention and community education through the collaborative efforts of community-based HIV/AIDS service organizations, hospitals and clinics.

The Circle provides comprehensive, family-centered care to families - infected children, their parent and affected siblings - in three Family Clinics located at The Children's Hospital of Philadelphia, St. Christopher's Hospital for Children and The Care Plus Clinic at Strawberry Mansion District Health Center. All families receive *case management* either through a hospital based social worker or a case manager from ActionAIDS. Families with the most intensive needs are assigned a Case Manager Assistant (CMA), a woman from the community who has been specifically trained to provide both practical and social/medical support to the families . ActionAIDS, Philadelphia Community Health Alternatives (PCHA) and Congreso de Latinos Unidos provide CMA services. The Family Clinics provide all *primary medical care* for both the infected child and mother during the same visit, and well child care for the uninfected siblings. Families also receive counseling and access, to the various clinical trials in the Philadelphia community. Support services such as drug and alcohol counseling, in home respite care provided by EIARC, housing counseling, nutrition education, grants for urgent daily living needs (Fund for Families), transportation and baby sitting are provided. In addition support groups are accessed through the social service and clinical sites.

The Circle of Care provides *outreach, prevention and community education* through PCHA, Congreso, BEBASHI, Spectrum Health Services and WATS. These agencies target the disenfranchised communities of the City, particularly communities of color, women and adolescents, who are at more significant risk for HIV infection. These community organizations also provide HIV counseling and antibody testing.

In 1995, the Women's Initiative (WIN), to reduce perinatal transmission was added to the Circle. This project targets pregnant women who are at risk for HIV in prenatal clinics throughout Philadelphia, providing education on perinatal transmission, HIV counseling and antibody testing, ZVD counseling and case management The women enrolled in the case management services of WIN have the choice of accessing the other services of the Circle, including post partum care at the Family Clinics.

The Circle of Care has numerous collaborative relationships such as training through the Pennsylvania AIDS Education Training Center; Drug and Alcohol services by Achievement Through Counseling and Treatment (ACT) and housing for families with Friends Rehab Association. It occupies board seats on public policy bodies, such as the Philadelphia AIDS Consortium and the HIV Regional Planning Commission.

The Circle of Care provides medical care in three comprehensive medical clinics that offer primary and some specialty medical care to all family members - adults as well as children - at the same place and time.

These three Family Clinics are at the heart of The Circle of Care. Here, families receive comprehensive, family centered care for the entire family, infected adults, infected and affected children and youth, Our unique approach to "one stop shopping" is that the entire family is seen on the same day at the same place.

The Family clinics were designed to make life easier for a family to access health care and social services. On site at the three clinics, all families can receive well child and specialty care, gynecological care, substance abuse counseling, housing assistance, risk reduction education, social work services, legal assistance, case management, emergency funds, access to clinical trials, nutrition education and support groups.

Two clinics are in pediatric hospitals, The children's Hospital of Philadelphia and St. Christopher's Hospital for Children; the third is in a community-based city health center. As of March 1997. The family clinics were serving 881 families, including 250 children who are HIV positive, 82 with AIDS and 44 adolescents who are HIV positive. At each clinic session, families also get support services: case management and/or social work services, nutrition education, risk reduction, drug and alcohol, and housing counseling.

St. Christopher's Hospital for Children (SCHC) and The Children's Hospital of Philadelphia (CHOP) radically changed service delivery to offer family-centered care. Arrangements with Temple Hospital and the Hospital of the University of Pennsylvania (HUP) allow internists and adult nurse practitioners to provide primary care to adults in these pediatric hospitals. Then, as the number of affected families enrolled in the family clinics grew dramatically, The Circle asked for and received funding for a community-based family clinic: the Care Plus Clinic in the City of Philadelphia's Strawberry Mansion District Health Center.