REVISE 12/1/97

FIRST LADY HILLARY RODHAM CLINTON
STATEMENT FOR WORLD AIDS DAY
NATIONAL THEATER
WASHINGTON, D.C.
DECEMBER 1, 1997

Acknowledgments: From advance.

Thank you. I am deeply grateful for this award. I accept it with the realization that when it comes to fighting AIDS, there are no lasting honors -- there are only continuing challenges. Challenges to do better. To find a vaccine. To develop treatments faster. To educate people more effectively. To make life better for those with HIV. To protect those without the virus from ever contracting it -- particularly our children.

I know every person in this room has worked to advance these goals. And that because of this work, we are -- on this World AIDS Day -- closer to them than we were a year ago.

I also know that many of us are here today because we were inspired by the example of someone who is not here with us this afternoon: Elizabeth Glaser.

I first met Elizabeth in the summer of 1992. She spoke to thousands of delegates at the Democratic National Convention and millions of Americans watching at home on TV.

Her words woke up the world to the urgency of the AIDS crisis. She also made clear the grim fact that AIDS hits children especially hard. Children with HIV have fewer options for treatment and care than adults.

Elizabeth helped to start the Pediatric AIDS Foundation in large measure because of her struggle to get medication for her young daughter, Ariel, and for other children with AIDS. Elizabeth contracted HIV from a blood transfusion she received shortly after giving birth to her daughter. The virus was passed to Ariel. Yet while Elizabeth was able to take AZT to fight the disease, Ariel was not. Elizabeth was one of the first to recognize that medical treatments that are saving adult lives are too slow in finding their way to children.

The Pediatric AIDS foundation exists today because Elizabeth refused to see herself and her child as victims of fate. Elizabeth understood that in order to bring hope, you must fight against despair -- and that you can always find more meaning in your own life by helping others.

I will always treasure the time Elizabeth and I spent together talking about our children, our lives and our concerns. I cannot forget the fact that she would have celebrated her 50th birthday this year. I am sure she would be honored that this organization that is synonymous with her name, now bears her name -- the Elizabeth Glaser Pediatric AIDS Foundation. I know she would be honored by the fact that all of you are carrying on her mission.

For there is still much to do.

When it comes to children living with HIV and AIDS, we have reason to be both hopeful and concerned. We should be hopeful because of the outstanding research being performed daily by our scientists and doctors. And we should be concerned because some of the latest treatments are not yet available to them. In fact, of the eleven drugs currently approved for the treatment of HIV and AIDS, only six are approved and formulated for children.

We should be hopeful because the Centers for Disease Control announced this spring that for the first time since the AIDS epidemic started in 1981, the number of AIDS deaths dropped. So did the number of reported cases of mothers transmitting HIV to their babies, which fell by 27 43 percent. But we should be concerned that by the Year 2010 as many as 40 million children will have lost their parents to AIDS.

There have been many successes in the fight against AIDS, among them innovative drug therapies and aggressive treatments. Over the last five years, funding for AIDS research has increased by more than half. Initiatives that help low-income, uninsured people with AIDS pay for treatments have tripled. Drug assistance programs for AIDS patients have increased four-fold.

This summer, the President announced a plan to see to it that important medications are tested and made available to children more effectively and safely than ever before.

This plan will see to it that children have access to the same newly developed drugs as their parents. It will ensure that doctors know what medicine works for children -- and how much to give. And it will give parents and doctors the peace of mind that comes from knowing that if a drug is available, and it can help a child, then we will be able to use it.

Last I saw many of you was at the annoucement of this regulation. Now the comment period has ended and the regulation is moving forward. We had a lively comment period, which is what we hope for. A wide range of views were expressed. But only one view was predominant: This initiative will save children's lives. The comment period made clear that doctors, nurses, hospital administrators, consumer advocates and parents support this regulation overwhelmingly. They believe it is one of the most significant advances in drug treatments for children in decades. They know that when it comes to caring for our children, guesswork just isn't good enough.

Seeing to it that our children get cutting edge medicine faster is just one more step. Together, I know we will do more -- as parents and advocates, as researchers and doctors. We will act in the name of Elizabeth Glaser. We will act in the name of the remarkably brave and strong children who are confronting this disease. We will act in the hope that one day we will no longer have to mark World AIDS Day.

American Academy of Pediatrics

Department of Government Liaison
American Academy of Pediatrics
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Web Site: http://www.aap.org

December 1, 1997

The Honorable William Jefferson Clinton
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear President Clinton:

The American Academy of Pediatrics (AAP) reaffirms our support for your Administration's efforts and commitment to advancing the health of our nation's infants, children and adolescents through the proposed regulations to require manufacturers to assess the safety and effectiveness of new and already marketed drugs and biological products for pediatric patients. These regulations are necessary to ensure informed use of drugs for children because, under current regulations, most drugs enter pediatrics without study in children and only after use in adults. Pediatric drug testing and labeling is a step that should be taken without hesitation.

The AAP does not underestimate the opposition that might be mounted against the recommendation that all drugs be studied in children if the disease occurs in children. However, arguments against this position can not pass the "ethics" test. Within the proposed rule, the FDA seeks comments on ethical issues that may be raised by this proposal. Clearly, the most basic of ethical issues is the implication of administering drugs and biological products to pediatric populations without adequate information. This is no greater a medical ethical dilemma than that posed for those who treat children: to give a drug with sufficient information on safety and efficacy, or to withhold treatment and let the disease progress unabated.

Proper studies must be done to ensure that children receive optimal treatment. Currently, only 20 percent of all drugs marketed in the United States have been labeled for use by infants, children or adolescents. For example, asthma is the leading cause of hospitalization of children in the United States, and commonly affects children younger than age 5. Despite that, there is only one asthma drug labeled for use in children under the age of 6.

The impact of these proposed regulations, properly implemented, cannot be understated. Pediatricians and other health care professionals will have available more precise information that takes into account various stages of child development so that the best drug, at the right dose, can be prescribed.

Sincerely,

Joseph R. Zanga, M.D.

Joseph R. Zanga, M.D., FAAP
President

JRZ:kbf

National Association of
Children's Hospitals

LAWRENCE A. McANDREWS, FACHE
President & Chief Executive Officer

N • A • C • H

December 1, 1997

The President
The White House
Washington, DC 20500

Dear Mr. President:

Having recently submitted our detailed comments on the proposed Food and Drug (FDA) rules on testing of pharmaceutical products for pediatric use, I want to reiterate our association's strong commitment to your administration's efforts to ensure the safety and efficacy of pharmaceuticals for children.

Children's health care does not command the attention of the health care market place, because children represent less than 30 percent of the population, less than 15 percent of personal health care spending, and the poorest segment of society. It is not surprising that only about 20 percent of all drugs marketed in the United States have been tested and labeled for use by children. This lack of focus on children would not be a problem, if children's health care needs were the same as adults' needs. But, that is not the case.

The FDA's proposed rules, along with provisions in the new FDA reform legislation, seek to ensure the market's focus on children's needs by leveling the playing field for manufacturers through federal regulation. As we proposed in our written comments on the proposed regulations, all drugs should be presumed to be subject to testing. A panel of pediatric experts, recommended by the American Academy of Pediatrics and others, would be responsible for advising FDA on those instances in which testing of a particular product would not be necessary. And certainly it is our expectation that pediatric testing requirements should not impede the marketing of products for adult use.

The goal of the FDA proposal reflects not only prevailing judgment among pediatric providers but also the personal commitment of the First Lady and yourself to policy that helps every family meet its children's needs for health, education, safety, and security. Such a family-centered commitment is at the heart of every children's hospital's mission of service to its community.

Sincerely,

Lawrence A. McAndrews

Lawrence A. McAndrews

401 Wythe Street, Alexandria VA 22314
(703) 684-1355 Fax (703) 684-1589

November 25, 1997

MEMORANDUM FOR HILLARY RODHAM CLINTON

FROM: **Brenda Costello**
SUBJECT: **Briefings for Monday, December 1**

World AIDS Day Event
-Briefing
-1997 World AIDS Day Program
-Bios
-President Clinton's World AIDS Day message
-Administration World AIDS Day Activities
-A Statistical Portrait of the HIV/AIDS Epidemic
-Pediatric Labeling Q & A
-Announcement of new regulation for Safe Use of Medications to Treat Children
-Children's Health background

Videos
-Briefing and scripts prepared for the President (to be forwarded by Staff Secretary)

Remarks
-World AIDS Day Event

November 25, 1997

WORLD AIDS DAY EVENT

DATE:	**Monday, December 1**
TIME:	**12:15 pm - 1:30 pm**
LOCATION:	**Helen Hayes Gallery, National Theater Washington, D.C.**
FROM:	**Brenda Costello**

I. PURPOSE

To deliver remarks at the Pediatric AIDS Foundation's 1997 World AIDS Day Event and accept their first "Commitment to Children Award."

II. BACKGROUND

In recognition of this year's World AIDS Day theme, "Give Children Hope in a World with AIDS," the Pediatric AIDS Foundation (PAF) is hosting an event on Monday at the National Theatre. World AIDS Day is dedicated to drawing national attention to the issues surrounding HIV/AIDS. This year, the Pediatric AIDS Foundation (PAF) is hosting an event to educate and enlighten people on how difficult it is to be a child living with HIV/AIDS. The Foundation will also present you with the first "Commitment to Children Award."

The messages that the Foundation are trying to convey are that children who have HIV/AIDS suffer mentally as well as physically, and that despite much good news about AIDS, that news applies to only a small percentage of children. Until there is a cure and vaccine for HIV/AIDS, the issue of pediatric HIV/AIDS must be a priority. PAF also helps to bring to attention the fact that children live every day with a combination of hope and fear of the future. Additionally, children do not yet have access to 100% of the drugs on the market to treat HIV/AIDS, and infants and newborns do not have access to protease inhibitors.

Last year 400,000 children under the age of 15 became infected with HIV/AIDS worldwide, and by the end of 1997, UNAIDS estimates that one million children will be living with HIV. Adolescents currently represent 25 percent of new HIV infections in the U.S., meaning two adolescents are infected every hour. Women of childbearing age also make up an ever-increasing population of people contracting HIV. (See additional statistics attached)

The Elizabeth Glaser Pediatric AIDS Foundation

Monday's event will also officially unveil a new name for the Pediatric AIDS Foundation. It will become "The Elizabeth Glaser Pediatric AIDS Foundation," as a way of reaffirming the vision, passion and dedication Elizabeth Glasser inspired in co-founding PAF.

The audience will be comprised of approximately 100 guests, including thirty third-grade students from the Janney Elementary School in Washington, D.C. and 75 adults -- donors, friends of the Foundation and NIH representatives. The students were chosen to participate to promote AIDS education and awareness among children and youth. Over the last month, their school nurse has been providing information to the students to prepare them for Monday's event. Paul and Elizabeth Glaser's son Jake, now 13, is expected to attend.

Note: The artwork on display at the event, called mandalas or a "circle of expression", is used by Dr. Lori Weiner as art therapy. These mandalas will be on display in the stairway, in the Gallery behind the audience, and will be printed each program as well. Susie Zeegen will refer to this artwork in her remarks.

Format

The program will include remarks by Roger Dickson, CEO of the Foundation and Master of Ceremonies, Kate Schindle, 1998 Miss America, Mary Steenburgen, who as you know is the new Foundation National Spokesperson, and a short performance by the cast of "Bring in Da Noise Bring in Da Funk."

A 10 minute play will be performed by five local Washington actors, all adults, and is a "conversation" based on actual discussions with children about HIV/AIDS. Following the play, a brief question and answer session will take place with Dr. Lori Weiner from NIH and 3 teens associated with the Foundation who are "public" and have been involved in other PAF events.

As Paul Glaser presents you with your award, two third-graders from the Janney Elementary School, Ian Collins and Kristen Smith, will present you with a (thank you) card. (Guests will be escorted upstairs for a reception as you depart)

III. PARTICIPANTS

-The First Lady
-Susie Zeegen, Co-founder, Pediatric AIDS Foundation
-Roger Dickson, CEO, Pediatric AIDS Foundation and Master of Ceremonies
-Kate Schindle, 1998 Miss America
-Lori Weiner, Coordinator, Pediatric HIV Psychosocial Support Program, National Institutes of Health

-Mary Steenburgen, National Spokesperson
-Paul Glaser, Chairman of the Board of Directors, Pediatric AIDS Foundation
-Bring in Da Noise, Bring in Da Funk cast

IV. SEQUENCE OF EVENTS

- The First Lady
- Susie Zeegen, Co-founder, Pediatric AIDS Foundation makes welcoming remarks and introduces Roger Dickson, CEO, Pediatric AIDS Foundation.
- Roger Dickson introduces Kate Schindle, Miss America 1998.
- Kate Schindle introduces the short play, "Coming to Terms".
- 10 minute play, "Coming to Terms" is performed.
- Roger Dickson introduces Lori Wiener, Coordinator, Pediatric HIV Psychosocial Support Program, NIH.
- Lori Wiener introduces three HIV-infected children, Hydeia Broadbent, Joey DiPaolo, and Tanya Torres, and takes questions from the audience.
- Susie Zeegen introduces the new Pediatric AIDS Foundation spokesperson, Mary Steenburgen.
- Mary Steenburgen makes brief remarks.
- Susie Zeegen and Paul Glaser make remarks.
- Paul Glaser presents the Commitment to Children Award to the First Lady and invites two children on stage to present the First Lady with a card.
- The First Lady makes remarks.
- Upon conclusion of the First Lady's remarks, Roger Dickson makes closing remarks and introduces Bring in Da Noise, Bring in Da Funk.
- Bring in Da Noise, Bring in Da Funk performs a piece from their show.
- Upon conclusion of performance, program is ended and the First Lady departs

V. PRESS

Open press.

VI. REMARKS

Provided by Sanjay Gupta.

PROGRAM
1997 World AIDS Day

Welcome
Susie Zeegen
Co-founder, Pediatric AIDS Foundation

World AIDS Day Introduction
Roger Dickson
CEO, Pediatric AIDS Foundation

"Coming To Terms"
a conversation created by Nick Olcott
from the words of young people with AIDS
Directed by Dr. Donn B. Murphy
Introduced by Miss America 1998, Kate Shindle

Question & Answer Session
Lori Wiener, Coordinator, Pediatric HIV Psychosocial Support Program
National Institutes of Health
Hydeia Broadbent, Joey DiPaolo and Tanya Torres

Message From National Spokesperson
Mary Steenburgen
Pediatric AIDS Foundation Spokesperson

Message From the Foundation
Susie Zeegen
Paul Glaser
Chairman of the Board of Directors, Pediatric AIDS Foundation

Commitment to Children Award Presentation
Paul Glaser

Honoree
First Lady of the United States of America
Hillary Rodham Clinton

Bring in Da Noise Bring in Da Funk

Lunch Reception

Special thanks to: Dr. Donn Murphy and the National Theatre, Sandy Brock, Nick Olcott, Joe Fab, Dr. Lori Wiener, Steve Cupo, Steve Dawn, Monica Laufer, Ariane Nalty, Brenden Varma, Miss America 1998 Kate Shindle, Bring in Da Noise Bring in Da Funk , Hawaiian Natural Water Company, and The Greater Washington, D.C. McDonald's Restaurants.

Pediatric AIDS Foundation Co-founder Bios

Susan DeLaurentis: Susan went to Virginia Commonwealth University and worked in retail management from 1970 - 1979. In 1988 Susan co-founded the Pediatric AIDS Foundation, and as a friend and co-worker of Elizabeth Glaser's, Susan has adopted this issue to be a priority in her life. She directs all of the foundation's scientific programs.

Susie Zeegen: Susie received her B.A. in English from UCLA in 1969, and a M.A. in Educational Psychology, from Cal State University Northridge in 1978. Susie trained as a child development specialist in play therapy for hospitalized children at UCLA, and created exhibits at the Los Angeles Children's Museum. In 1988, as a friend of the Glaser family, Susie co-founded the Pediatric AIDS Foundation, and coordinates all fund raising and special events projects for PAF.

Roger Dickson
Chief Executive Officer
Pediatric AIDS Foundation

Roger Dickson was appointed Chief Executive Officer of the Pediatric AIDS Foundation in April 1997. Prior to joining the Foundation, he served for twenty-five years in various social service and biomedical management capacities with the American Red Cross at locations across the country. Most recently, Dickson served as Chief Executive Officer of the American Red Cross Bay Area headquartered in San Francisco, California. While in San Francisco, he restructured and reorganized that Red Cross Unit following the devastating Loma Prieta earthquake and shaped the organization to prepare for future catastrophic events. Dickson also served as Chairman of the State Public Policy Consortium, lead statewide strategic planning efforts, chaired the California State Executive Director's Association and served on numerous national, statewide and Bay Area regional committees. He is recipient of the 1995 "Women in Communications" Award for non-profit leadership and the Red Cross Presidential Ambassador's award for his achievements in promoting Cultural Diversity.

Roger is a native of southern California and is a graduate of the University of California, Los Angeles. He lives in West Los Angeles, California.

Miss America 1998
Kate Shindle

HOMETOWN
Evanston, Illinois

Age: 20

EDUCATION

Northwestern University Senior

Pursuing a double major in theater and sociology

AMBITION

To pursue a career in musical theater

PLATFORM

On the Way to a Cure: Preventing HIV Transmission in America

"We have within our power the ability to stop HIV in its tracks. The answer is prevention, and it is currently the most viable solution to the AIDS epidemic. Prevention is something we all can do right now. If we all join in the race, we have the ability to break through the ribbon of victory and put an end to HIV and AIDS."

Platform Background & Experience

- Volunteer for Chicago's Test Positive Aware Network, the NAMES Project, the Center for AIDS Services, and several hospices;
- Has met with Sandy Thurman, Clinton Administration AIDS Czar; Senators Dick Durbin and Carol Moseley-Braun; and former Senator Harris Wofford, CEO of the Corporation for National Service;
- Has collaborated with leaders of the Centers for Disease Control, AmeriCorps, the National Minority AIDS Council, the National AIDS Fund, the American Federation of Teachers, and the National Education Association AIDS Project.

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On the Way to a Cure: Preventing HIV Transmission in America

Platform Statement of Kate Shindle, Miss America 1998

Every year, thousands of Americans with their whole lives before them are told they will have to fight for every tomorrow. They are all ages, all races. They are female, they are male. They are gay, they are straight. Hundreds of them are beautiful newborn babies. They have all been diagnosed with HIV, the virus that causes AIDS.

I don't even remember the first time I heard about AIDS. As a child who grew up with it as a part of our society, I only knew it was something that killed people. As a university student involved in theater and the arts, suddenly it was all around me, and my knowledge grew. But when a close family friend was diagnosed, the epidemic was given a human face and the war on AIDS became a personal crusade.

Two roads in my life met this year. As an AIDS volunteer pursuing the title of Miss America, I recognized the possibility for my personal commitment to touch the lives of young people nationwide. I also saw an opportunity to turn the spotlight where I felt it was needed most -- on HIV prevention.

We have within our power the ability to stop HIV in its tracks. The answer is prevention, and it is the *only* solution to this deadly epidemic until a vaccine and a cure can be found. Without question, prevention is wholly effective in stopping the spread of HIV, and its power must not be ignored.

As we work toward a cure, current treatments are extending people's lives and a variety of prevention programs exist in our schools, our communities, our nation. But something is wrong. Although fewer people are dying from AIDS-related illnesses, the number of HIV infections is ever growing. Not only do two American teenagers contract HIV every hour, but 8,500 new infections occur worldwide every day.

We need to stop the rhetoric and start taking action. Whether it's condom distribution, needle exchanges or just talking to our kids about sex, the time is long past for us to stop waiting passively for one solution. The decision to confront our inhibitions head-on is never an easy one, but while we bide our time and weigh our options, people are still dying.

As I travel the county as Miss America, I will focus my energies where the virus is spreading fastest -- among racial minorities, women, and especially among young people. I will actively promote all elements of the prevention equation, including sexual abstinence, monogamous relationships, safer sex, clean needles, testing and treatment.

To parents, educators, spiritual leaders, community activists, government officials and business people, I say set aside your biases, open your minds, and use your power to take an active role in preventing HIV transmission. Whether large city or small rural community, I ask you to *accept* the facts of the epidemic, *understand*, that it affects all people, and *fight* to engage whatever strategy is most appropriate and effective in saving your children, your families and your neighbors.

I will support AIDS organizations and all those who educate people and arm them with practical prevention skills. I will encourage additional funding for prevention programs. I will endorse affordable, accessible and quality care for those who are already infected and sometimes forgotten. And I will actively promote the availability of free and anonymous testing, so that all Americans will be able to determine their HIV status and take appropriate action.

But most importantly, I will speak to my generation. I will direct the Miss America spotlight away from myself and toward their overwhelming need for HIV prevention. I will work to ensure that all young people can confidently make educated choices and empower them to respect themselves, believe in themselves and protect themselves. I will use both my age and my position as Miss America to reach my peers and all young people as never before.

And because I understand that the AIDS epidemic is as complex as it is catastrophic, I will listen as much as I speak, so that the voices and needs of the individuals affected by HIV and AIDS will be heard across our nation.

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THE WHITE HOUSE

Office of the Press Secretary

REMARKS BY THE PRESIDENT
IN VIDEOTAPED MESSAGES FOR WORLD AIDS DAY

THE PRESIDENT: I'm pleased to take part in this commemoration of World AIDS Day. Today we have good reason to be hopeful. Powerful new treatments are helping people with AIDS to live longer and healthier lives. But the epidemic continues. HIV is affecting more and more young people. So this year let me send a special message to young Americans.

Only you have the power to keep yourself safe. Get the facts about HIV and AIDS, and use them. This deadly virus does not discriminate. It takes advantage of anyone who puts himself or herself at risk. Don't let HIV keep you from reaching your dreams. You're important to your family, your friends, to all the rest of us as well, but you must take responsibility for your health, your education, and your safety. Reach out to the adults in your lives for advice and support.

And one last thing -- talk to each other, share the facts with your friends and your peers, become a part of the solution. We must fight ignorance with education. We must fight fear with facts. And most importantly, we must fight AIDS, not people with AIDS.

Always remember to respect yourself, protect yourself, keep believing in your future; for America's future depends on you.

Well, Hillary, I want to congratulate you on receiving the Pediatric AIDS Foundation's Commitment to Children Award. It's no secret that I think my wife has been an extraordinary and tireless advocate for children throughout all the years I've known her. So let me also thank the Foundation for recognizing her lifetime of work. And I thank the Pediatric AIDS Foundation for your own leadership and commitment to helping children with AIDS live longer and happier and healthier lives.

DRAFT

FEDERAL WORLD AIDS DAY ACTIVITIES

Department of Commerce

Activities: Will conduct a workshop on "How to Talk to Your Kids about AIDS and another workshop focusing "Management Concerns": Addressing HIV/AIDS Issues in the Workplace." A film titled, "After Goodby: An AIDS Story" will be shown, as well as the film on he AIDS memorial quilt, "Common Threads: Stories from the Quilt."

Time: 10:00 a.m - 2:00 p.m

Place: HCHB Conference Room 48309

Contact:

Corporation for National Service

Activities: Many of the 189 local AmeriCorps volunteers working on HIV/AIDS issues will attend the AIDSCAP press conference at the National Press Club. They will then attend the District of Columbia's Agency for HIV/AIDS's AIDS Fair; the volunteers will then attend an event Miriam's House.

Time:

8:30 a.m.	AIDSCAP Press Conference (National Press Building)
11:00	AHA AIDS Fair
TBD	Miriam's House

Place: See Above

Contact:

Department of Energy

Activities: The Department of Energy will display a panel from the National Memorial AIDS Quilt; an award winning documentary "Our Faces,:" will be shown on both December 1 and 2; will dim the lights of all D.C. and Germantown buildings, as will be done at the White House; volunteers from the Department's Gay, Lesbian and Bi-sexual Employees organization (GLOBE) will distribute red ribbons and a listing of local AIDS service organizations; an E-mail listing of all AIDS Day events will be sent to all DOE employees; a WEB page linking users to HIV/AIDS service providers will be developed; and a member of the Children's HIV/AIDS Model Program will speak to the Diversity Council about activities focusing on children.

Time:

All day	Quilt; "Our Faces" video, distribution of red ribbons
7:45 p.m.	Dimming of Lights

Place: Main building entrance

Contact:

DRAFT

Department of Housing and Urban Development

Activities: In addition to red ribbons being handed out by the HUD Gay Lesbian and Bi-sexual Employees groups (GLOBE), a large 80' red ribbon will be displayed in the main lobby. In addition, HUD's Employee Assistance Program (EAP), together will the HUD Health Unit, will staff an AIDS information table. All HUD employees will receive a focus message from the EAP focusing on HIV/AIDS.

Time: All day

Place: Main lobby

Contact:

Department of Justice

Activities: Attorney General Janet Reno is scheduled to give remarks at the DOJ commemoration titled "Faces of AIDS: Giving Hope for the Future." In addition, Precious Thomas, a child living with AIDS, will also speak. Jim Graham, executive director of Whitman-Walker Clinic in Washington, D.C., the area's largest AIDS service organization, will also provide remarks. It is anticipate that a DOJ employee with AIDS and family members of an employee who dies from AIDS will also speak.

Time: 10:00 a.m.

Place: Main Justice Building, Conference Room B

Contact:

Office of Personnel Management

Activities: OPM will show the video and photo display from the Boston to New York AIDS Ride, a bicycle ride completed by several thousand individuals over a three-day period. In addition, OPM staff will distribute information about local AIDS service organizations.

Time:

Place:

Contact:

U.S. Peace Corps

Activities: Volunteers in approximately 90 host countries will be conducting their own World AIDS Day activities in their post around the world.

Time: n/a

Place: n/a

Contact:

DRAFT

Social Security Administration

Activities: The Commissioner of the SSA will send a letter to the nearly 65,000 SSA employees acknowledging World AIDS Day and detailing resources available to employees who may have concerns or questions.
Time: n/a
Place: n/a
Contact:

U.S. Department of State

Activities: Both Miss America and Sandy Thurman, Director of the Office of National AIDS Policy, will help the State Departments commemorate the theme for World AIDS Day, "Give Children Hope in a World with AIDS. The Deputy Secretary of State will host the program. Jim Graham, executive director of Whitman-Walker Clinic in Washington, D.C. and chair of the board of directors of the National Association of People with AIDS, and USAID Administration Brian Atwood or Ambassador Sally Shelton will participate. Approximately 350 people will attend, including 20 - 30 children affected by HIV/AIDS.
Time: 12:00 noon
Place: State Department
Contact:

U.S. Information Agency

Activities: USIA's news services will highlight US activities scheduled to mark World AIDS Day. News service programs will provide fresh news items, and identify new contacts for the development of upcoming international exchange programs.
Time: All day
Place: n/a
Contact:

Department of Veterans Affairs

Activities: VA facilities will mark World AIDS Day with special displays, distribution of literature, and other education programs. VA's main headquarters will have a display and distribution of HIV/AIDS awareness literature.
Time: All day
Place: Main lobby
Contact:

December 1997

THE WHITE HOUSE

WASHINGTON

A STATISTICAL PORTRAIT OF THE HIV/AIDS EPIDEMIC

OFFICE OF NATIONAL AIDS POLICY

GLOBAL PICTURE:

- UNAIDS estimates that there are 30.6 million persons living with HIV/AIDS
- Since the epidemic's onset, 11.7 million adults and children have died of AIDS; 2.3 million will die in 1997
- 1997 will witness a total of 5.8 million new HIV infections, equivalent to 16,000 per day
- The majority of new infections is among 15-24 year olds
- 75-85% of new infections are due to unprotected sexual intercourse (70-75% heterosexual, 5-10% male-male), 5-10% are due to intraveneous drug use, and 3-5% result from blood transfusions
- 90% of all HIV+ persons live in developing countries, where access to medical care is severely limited

ACROSS THE NATION:

- Over 600,000 AIDS cases have been reported to the CDC through June, 1997
- CDC estimates that between 650,000 and 900,000 Americans are currently living with HIV, with between 40,000 and 60,000 new infections occurring each year
- Over half of new HIV infections are due to sexual intercourse, one quarter result from intraveneous drug use
- AIDS incidence declined for the first time in 1996 by 6%; however, incidence rose by 9%among persons infected heterosexually, and the number of new HIV infections continues to increase
- AIDS related deaths declined by 23% in 1996, due largely to access to effective combination drug therapy
- Number of people living with AIDS rose by 11% in 1996
- AIDS is the second leading cause of death among adults ages 25-44
- AIDS is the leading cause of death among all federal & state prisoners

STATUS OF WOMEN:

- Women account for 42% of adults living with AIDS, 20% in the United States
- Major mode of HIV transmission to women is unprotected heterosexual intercourse
- In 1996 AIDS incidence rose 2% among U.S. women even though it declined 8% among men
- The total domestic increase in AIDS incidence among women since 1991 is 70%, leaving women the fasting growing group with AIDS in the U.S.

AMERICAN COMMUNITIES OF COLOR:

- In 1996, 62% of all persons with AIDS (reported) and over 79% of women with AIDS cases were minorities
- AIDS incidence is 3 times higher among Latinos and 7 times higher among blacks than whites
- Incidence is 6 times higher among Latino women and 17 times higher among black women than white women
- More than three quarters of all pediatric AIDS cases are in racial and ethnic populations

PERINATAL TRANSMISSION OF HIV:

- 2000 babies are born HIV+ in the United States each year, equivalent to 5 per day
- There is a 25% probability that an HIV+ woman will transmit the virus to her unborn child
- Treatment with AZT reduces the likelihood of perinatal transmission to 5%
- Perinatal transmission dropped 43% in the U.S. between 1992 and 1996 due to increased use of AZT

AIDS AMONG CHILDREN & YOUTH:

- 1.1 million children under the age of 15 are living with HIV/AIDS around the world
- Since the epidemic's onset, 2.7 million children have died of AIDS; 460,000 will die in 1997, 1200 per day
- 1997 will witness a total of 590,000 new HIV infections among children, equivalent to 1600 per day
- If the spread of this virus is not contained, 40 million children will be orphaned by AIDS worldwide and global infant mortality will rise 75% due to AIDS by 2010
- In the United States, half of all new HIV infections are among persons under the age of 25
- AIDS is the sixth leading cause of death among 15-24 year old Americans

BRIEFING PAPER FOR WORLD AIDS DAY EVENTS

State of the Epidemic - United States

- New infections per year = 40,000 to 60,000
- New treatments and better care resulted in a 23% decline in AIDS deaths in 1996
- Fewer deaths means more people living with HIV and AIDS
- HIV is moving rapidly among African-Americans, Latinos, women, and young people
- Total AIDS cases to date = 612,000 (of which 237,000 are still alive)
- Total HIV positive = 600,000 to 900,000 (conservatively)

State of the Epidemic - Global

- New infections = 5.8 million per year (just announced by World Health Organization)
- New estimate by UNAIDS of children orphaned by AIDS = 40 million by 2010
- Total living with HIV/AIDS = 31 million
- Total deaths to date = 12 million (2.3 million in 1997)
- 90% of new infections occur in developing world
- Majority of new infections among 15-24 year olds

Pediatric AIDS

- 2,000 babies are born HIV infected in the U.S. each year - 5 per day
- perinatal transmission dropped 43% in US between 1992 and 1996 - treatment with AZT
- More than 75% of all pediatric AIDS cases are among people of color

Youth and AIDS

- Half of all new HIV infections in US are among youth under 25
- AIDS is 6th leading cause of death among 15-24 year old Americans

People of Color and AIDS

- In 1996, 62% of all persons with AIDS and 79% of women with AIDS were minorities
- The incidence of AIDS is 7 times higher among African-Americans and 3 times higher among Latinos than among white Americans

Women and AIDS

- African-American women are 17 times more likely and Latinas are 6 times more likely to get AIDS than their white counterparts
- women account for 42% of adults living with AIDS worldwide, and 20% in US

Domestic Funding

- Discretionary AIDS funding increased over 60% since start of term
- AIDS researhc funding increased by over 50% in four years
- AIDS Drug Assistance Program funding up 450% since 1996
- Tripled funding for the Ryan White CARE Act
- Prevention funding to Centers for Disease Control up 27%

PEDIATRIC LABELING Qs and As

Q: WHY ARE YOU DOING THIS REGULATION NOW?

A: Despite efforts to increase the number of studies on pediatric populations, still too many children take prescription drugs that have not been tested on children. Over 80 percent of drugs manufactured in the United States have not been tested on children and over 50 percent of drugs that are known to be widely tested in children have not been tested.

As a result, some physicians are reluctant to prescribe much-needed therapies to children. Physicians report that they have denied children important new drugs because, in the absence of adequate testing and labeling, they would have to guess at an appropriate dosage, and they do not want to take that risk.

In some cases, guessing can be extremely dangerous. One example of the possible harm is the case of "gray baby syndrome" where a number of babies died from chloramphenicol, an antibiotic that their immature livers were unable to accept. Other children have had withdrawal symptoms from prolonged administration of fentanyl, a pain killer used as an adjunct to anesthesia in infants and small children. Still others have suffered seizures and cardiac arrest from bupivacaine, a local anaesthetic not adequately tested in pediatric populations.

Q: CAN'T YOU ACHIEVE THE SAME EFFECT THROUGH VOLUNTARY COMPLIANCE?

A: FDA has already implemented reforms to encourage voluntary compliance. However, as 80 percent of drugs manufactured in the United States and over 50 percent of drugs widely used in children still do not have a adequate pediatric labeling, FDA has concluded that this new rule is necessary to ensure that children get the protection they need.

Q: GIVEN THAT THE DRAFT FDA REFORM LEGISLATION, PENDING IN CONGRESS, CONTAINS FINANCIAL INCENTIVES TO ENCOURAGE VOLUNTARY COMPLIANCE, WHY IS THIS RULE NECESSARY?

A: The Congressional approach, while thoughtful and worthy of serious consideration, would not assure that most or all of prescription drugs used by children are tested and labeled appropriately. We believe that the Dodd/Dewine legislation has the potential to complement the regulation the President is unveiling today, but it is not a replacement for it.

Q: DO YOU SUPPORT THE DODD LEGISLATION AS CURRENTLY DRAFTED AS A COMPONENT OF THIS EFFORT?

A: We are reviewing this legislation to determine if it can be designed to compliment and bolster our efforts today. We believe that it has great potential to compliment the legislation but we are not prepared to accept it as currently drafted before we consider all of the ramifications of overlaying the important regulation the President is announcing today.

Q: HAVE CHILDREN BEEN AT RISK IN THE PAST?

A: Yes. In some cases physicians do not prescribe drugs because they determine that it is simply not worth taking the risk of prescribing drugs that have not been tested in children.

In other cases, physicians choose to prescribe treatment, because it is the only means to cure a child's nagging illness or even a life threatening disease. Those physicians are left to make their best guess at the appropriate doses -- rather than rely on the through studies and information that the rest of us take for granted.

In some cases, however, guessing can be devastating. One example of the potential for harm is the case of "gray baby syndrome" where a number of babies died from chloramphenicol, an antibiotic that their immature livers were unable to accept. Other children had withdrawal symptoms from prolonged administration of fentanyl, a pain killer used as an adjunct to anesthesia in infants and small children. Still others have suffered seizures and cardiac arrest from bupivacaine, a local anaesthetic not adequately tested in pediatric populations.

Q: HOW MANY PRODUCTS WILL BE AFFECTED BY THE RULE?

A: FDA anticipates that this will impact about 12 new drugs each year. The agency will also review drugs already on the market to determine which ones should have pediatric studies. FDA will work as quickly as possible to ensure that in a few years the drugs most important to children will have directions for use in kids on their labels.

Q: WHAT KINDS OF DRUGS ARE COMMONLY MISSING THIS PEDIATRIC DATA?

A: Drugs such as anti-asthmatics, steroids, drugs to treat gastrointestinal problems, strong pain medications, antidepressants, and antihypertensives commonly lack appropriate pediatric labeling.

Q: WHAT DO DOCTORS DO WHEN THEY DON'T HAVE THIS INFORMATION?

A: In some cases they choose not to prescribe the drugs at all. In other cases, they take their best guess -- without the assistance of information that we rely on for adult medications. Sometime, however, guessing can have dangerous consequences, such as seizures, heart problems, or even death.

Q: WHEN CAN PARENTS EXPECT THAT INFORMATION TO SUPPORT SAFE AND EFFECTIVE USE OF PRODUCTS IN CHILDREN WILL BECOME AVAILABLE?

A: We believe that, in some cases, the information already exists and the drug companies merely need to analyze and compile it. In these cases, the information can be made available on the labeling of the products fairly quickly. In other cases, studies need to be conducted. Under the requirements of FDA's 1994 regulation, where the effects of the product and the disease for which it is indicated are sufficiently similar in both adults and children, these studies can be done within one year.

Q: HOW MUCH WILL THIS COST DRUG MANUFACTURERS?

A: FDA estimates that the costs of pediatric studies will be less than 1% of the total costs of developing a drug.

Q: WILL DRUG PRICES INCREASE AS A RESULT OF THIS REGULATION?

A: Because the cost of pediatric studies to manufacturers is expected to be small, it is anticipated that there will be little or no price increases to patients.

Q: WILL THIS REQUIREMENT HOLD UP DRUG APPROVALS?

A: Clearly we will provide every incentive to complete the study before the drug is approved. However, the rule explicitly ensures that a drug's entrance into the market is not held up even if all studies on pediatric populations have not yet begun. We will rely on other legal and financial remedies to ensure that companies comply as soon as possible.

Q: WHEN WILL THIS REGULATION GO INTO EFFECT?

A: There is a 90 day period for comment on the proposed rule after which the agency will evaluate and respond to the comments and publish a final rule. The final rule will take effect 3 months after issuance. At that time, for drugs already on the market, FDA, in compelling circumstances, may request that pediatric studies be initiated. Manufacturers of new drug and biologic products, under review at the agency, will have 2 years to comply with the pediatric study requirement. Manufacturers of new products, not yet submitted for review, will have 18 months to comply with the requirement. Drugs already on the marketplace will have 3 months to comply.

Q: WHAT IS THE ENFORCEMENT MECHANISM FDA WILL TAKE TO FORCE COMPANIES TO PROVIDE THIS DATA ON APPROVED DRUGS?

A: FDA can go to court and ask the court to order the company to comply with the regulations. If the company does not comply, the court can impose penalties.

PRESIDENT CLINTON ANNOUNCES NEW MEASURES TO INCREASE AVAILABILITY OF INFORMATION ON SAFE USE OF MEDICATIONS USED TO TREAT CHILDREN

August 13, 1997

Today, President Clinton unveiled a new FDA regulation that will protect children by requiring manufacturers to study the safety and appropriate dosage levels of drugs for pediatric populations. The regulation also requires proper labeling of drugs for use in children. Even though many drugs affect children differently than adults, most drugs have not been tested on pediatric populations. Under this rule, manufacturers of prescription drugs likely to be used by children will be required to complete studies and place information on drug labels to help pediatricians and other health care providers make scientifically-based treatment decisions when prescribing drugs to children.

WHY THIS REGULATION IS NEEDED

Most drugs -- even those commonly used in children -- have not been widely tested on pediatric populations. According to the American Academy of Pediatrics, only a small fraction of drugs and biological products marketed in the United States have had clinical trials performed in pediatric patients. Despite evidence that drugs affect children differently than adults, 80 percent of all drugs marketed in the United States have been labeled for use by infants, children, and adolescents. Forty-two percent of drugs that are widely used in pediatric populations have been tested on children.

- Many drugs commonly given to children under the age of six including Prozac, Zoloft, Ritalin, and drugs for asthma, allergic reactions, and ear infections are inadequately tested and labeled for use in children. These drugs, taken together, are given to over five million children each year.

- Less than half of the drugs used in the treatment of HIV infections carry any safety or effectiveness information for children. Of those that do, the data is often incomplete.

- Safety and effectiveness information is especially sparse for the over seven million children under the age of two.

- The percentage of drugs being tested on children decreased by over one-third between 1996 and 1991.

Drugs are likely to have a different impact on children than on adults. The appropriate use and dosage levels of medication for children and adults is usually different because of disparities in organs, the immune system, and metabolism.

Children who take prescription drugs that have not been tested on pediatric populations are at serious risk for unexpected adverse reactions. Evidence suggests that prescribing drugs that have not been adequately tested on children can be extremely dangerous. One example of the possible harm is the case of "gray baby syndrome" where a number of babies died from chloramphenicol, an antibiotic that their immature livers were unable to accept. Other children had withdrawal symptoms from prolonged administration of fentanyl, a pain killer used as an adjunct to anesthesia in infants and small children. Still others have suffered seizures and cardiac arrest from bupivacaine, a local anaesthetic not adequately tested in pediatric populations.

Some physicians are reluctant to prescribe much needed therapies to children because they have not been tested on pediatric populations. Physicians report that they have denied children important new drugs because, in the absence of adequate testing and labeling, they would have to guess at an appropriate dosage, and they do not want to take that risk. As a result, too many children do not receive the treatment they need and deserve.

SUMMARY OF THE RULE

Pediatric Studies for New Drugs. Under this proposed rule, manufacturers of new drugs would have to do studies on pediatric populations under two circumstances: when the product represents a meaningful therapeutic benefit over existing treatments; or when the product is expected to be widely used on pediatric patients. The FDA anticipates that about twelve new drugs each year would meet this requirement. Manufacturers could receive waivers from the requirement to do a pediatric study under any one of the following circumstances:

(1) The product does not represent meaningful benefits over existing treatments and is not likely to be used on a substantial number of pediatric patients as a whole; or

(2) Necessary studies are impossible or highly impractical-- i.e., the number of patients is too small or geographically diverse; or

(3) There is evidence strongly suggesting that the product would be unsafe or ineffective in pediatric populations.

Pediatric Studies For Existing Drugs. For drugs that are already on the market, the new FDA regulation requires additional testing on the pediatric population only if there is a "compelling need for more information." The criteria used is:

(1) If the product is widely used in pediatric populations and the absence of adequate labeling could pose significant risks to pediatric populations; or

(2) If the product is indicated for very significant or life threatening illness, but additional dosing or safety information is needed to permit its safe and effective use in pediatric patients.

President Clinton Continues to Fight to Improve the Health of Our Nation's Children

- **Children and Prescription Drug Testing.** Today's announcement requiring manufacturers to do studies on pediatric populations for new prescription drugs and those currently on the market builds on an impressive array of children's initiatives advocated by President Clinton.

- **Children and Insurance Coverage.** The President fought hard to ensure that the Balanced Budget Act included $24 billion -- the largest investment in children's health care since the passage of Medicaid in 1965 -- to provide meaningful health care coverage to as many as five million of our nation's uninsured children. He also fought to include revenue from a 20 cent tobacco tax which will not only further reduce the number of uninsured children, but it will also serve as a financial barrier to help prevent our children from starting to smoke in the first place.

- **Children and Tobacco.** The President issued guidelines to eliminate easy access to tobacco products and to prohibit companies from advertising tobacco to kids. Each day about three thousand children become regular smokers and 1,000 of them will die from a tobacco-related illness. According to former FDA Commissioner David Kessler, the possibility of a comprehensive, public health oriented settlement with the tobacco industry could not have come about without the President's leadership in this area.

- **Children and Insurance Reform.** By signing the Kassebaum-Kennedy bill into law last year, the President helped millions of American children keep their health care coverage when their parents lose or change jobs.

- **Children and Juvenile Diabetes.** The President fought to include $150 million ($30 million annually for five years) for research to help find the cure for diabetes. Americans with this disease often suffer severe consequences, such as blindness and kidney disease, even when they receive the best treatment and care. The HHS Secretary will have discretion to target the new funds toward the best scientific opportunities. This represents the largest single new investment in Juvenile Diabetes.

- **Children and Immunization.** As the President recently announced, over 90 percent of America's toddlers in 1996 received the most critical doses of each of the routinely recommended vaccines -- surpassing the goal set by the President in 1993.

- **Children and the Environment.** Earlier this year, the President signed an Executive Order to reduce environmental health and safety risks to children by requiring agencies to strengthen policies and improve research to protect children and ensure that new regulations consider special risks to children.

- **Children and Medicaid.** Throughout his Administration, the President has fought to preserve and strengthen the Medicaid program; its coverage of about 20 million children, makes it the largest single insurer of children. The Administration has partnered with states through Medicaid waivers to expand coverage to hundreds of thousands of children.

To: Mrs. Clinton
Fr: Brenda Costello
Da: 12/1/97
Re: Additional background for World AIDS Day Event

Attached are talking points on recently released global HIV/AIDS statistics, as well as a bio of Dr. Lori Wiener, who will take questions from the audience at today's event.

TALKING POINTS FOR GLOBAL AIDS INCREASE
11/26/97

The UNAIDS Program is releasing new estimates of the number of persons infected with HIV throughout the world. These estimates show an increase from 3 million new infections per year to 5.8 million per year. Over 90% of these infections are occuring in the developing world.

What does this mean?
These new estimates show that the epidemic is much larger than expected, primarily in the developing world. Part of this increase is attributable to the spread of HIV, and part is due to improved data collection by UNAIDS and the World Health Organization.

What is the impact?
This epidemic continues to take a devestating human toll. And in many of the developing countries in which it is raging, AIDS represents a major threat to economic stability because it is decimating people in their most productive years.

What is the US response?
The United States has always been a leader in the global fight against AIDS. We are the largest contributor to UNAIDS, and one of the principal sources of prevention and care through USAID. In addition, the investment made in AIDS research will benefit not only those in this country but around the world. President Clinton's recently announced AIDS Vaccine Initiative, in which he established a goal of finding a vaccine against HIV within ten years, is absolutely critical. This epidemic cannot be stopped without a vaccine, and the United States is leading the world in this quest.

OTHER QUESTIONS THAT MAY BE RAISED RELATING TO HIV/AIDS

With the new treatments and the decrease in AIDS deaths, are we seeing the end of the epidemic?

The new drug treatments have helped many people with HIV and AIDS live longer and more productive lives, but they are a treatment, not a cure. We do not have any evidence that the rate of new infections has slowed this country. Globally, UNAIDS just released its estimate of new annual infections, which nearly doubled from 3 million per year to 5.8 million per year. More accurately, we are at the end of the beginning and not the beginning of the end. We must not let the good news of these promising treatments make us complacent.

What is the Administration doing on needle exchange?

This Administration fought to maintain the authority of the Secretary of HHS to remove the restriction on allowing states to use federal funds for needle exchange programs. The Secretary is gathering the scientific data on this issue in compliance with the directive of Congress. Decisions of this kind should be made by public health experts and scientists.

What is the US doing to help with the global epidemic?

The United States is the largest contributor to the UNAIDS program, a multinational effort to address the global AIDS pandemic. In addition, the USAID program through the Department of State is a leader in the provision of technical assistance, support, and prevention efforts in the developing countries where the epidemic is raging. The President's recent HIV Vaccine Initiative established a goal of finding a vaccine against HIV within ten years, and is the best hope of stopping this epidemic.

Are AIDS programs getting an unfair proportion of funding?

No. The AIDS epidemic is special. It is a contagious disease that strikes disproportionately in the young and the poor, and has a devastating impact on those who are in the most productive years of their lives. In addition, our investments in AIDS research provide a wealth of basic science information that benefits all diseases, including cancer and Alzheimer's.

How is the Administration helping to expand access to the new drug treatments?

We have increased funding for the AIDS Drug Assistance Program 450% since 1992, and have tripled funding for the program that helps people access and maintain care (Ryan White CARE Act). This is a growing challenge that will require a partnership between the federal, state and local governments and private industry.

THE NEW GLOBAL STATISTICS

People news infected with HIV in 1997	Total	5.8 million
	Adults	5.2 million
	Women	2.1 million
	Children < 15	590,000
No. of people living with HIV/AIDS	Total	30.6 million
	Adults	29.5 million
	Women	12.1 million
	Children < 15	1.1 million
AIDS deaths in 1997	Total	2.3 million
	Adults	1.8 million
	Women	820,000
	Children < 15	460,000
Total # of AIDS deaths since beginning of epidemic epidemic	Total	11.7 million
	Adults	9.0 million
	Women	4.0 million
	Children <15	2.7 million
No. of AIDS orphans since beginning of epidemic		8.2 million
Estimated no. of AIDS orphans by 2010		40 million

DAVID SHIPLEY [redacted]
11/26/97 06:26:35 PM

Record Type: Record

To: Jennifer L. Klein/OPD/EOP, Sanjay Gupta/WHO/EOP

cc: OMARY_M @ A1 @ CD @ LNGTWY
Subject: Re:

Thought you guys should see the following story. Do you want to check w/ our AIDS people to see if they want to alter the stats? If so, leave me a message over the weekend or call early on Monday. I'm going to send the version you guys have seen to HRC tonight. We can always fix stuff before the event.

Happy Thanksgiving.

David

---------- Forwarded by David Shipley/WHO/EOP on 11/26/97 06:25 PM ----------

Michael A. O'Mary
11/26/97 05:59:00 PM

Record Type: Record

To: David Shipley

cc:
Subject: Re:

Message Creation Date was at 26-NOV-1997 17:59:00

FYI:

Wednesday November 26 5:10 PM EST

U.N.: 16,000 a Day Infected With AIDS

By Evelyn Leopold

UNITED NATIONS (Reuters) - Aids cases soared worldwide to 30 million adults and children in
1997 with researchers saying they had grossly underestimated the rate of infection, now at about
16,000 a day.

The sharp climb -- from 22.6 million people in 1996 -- is due to new methods of collecting data as
well as an actual 19 percent increase in the results, said a report by UNAIDS, a joint program of

U.N. specialized agencies, released Wednesday.

But the increase, the survey said, is still 19 percent in 1997 over 1996 for all people infected with HIV or victims of Acquired Immune Deficiency Syndrome (AIDS), even when the new reporting methods are taken into account.

"We are now realizing that rates of HIV transmission have been grossly underestimated -- particularly in sub-Saharan Africa, where the bulk of infections have been concentrated," said Dr Peter Piot, executive director of UNAIDS.

"If current transmission rates hold steady, by the year 2000, the number of people living with HIV or AIDS will soar to 40 million," he said.

In 1997 alone, people who became infected for the first time swelled from 3.1 million children and adults to 5.8 million, an actual increase of 9 percent, according to the new estimates.

The report said that some 2.3 million people died of AIDS in 1997 -- a 50 percent increase over 1996. Nearly half those deaths were women and 460,000 were children under 15.

For children, the report estimates that 1,600 under 15 are infected with HIV every day compared to 1,000 children a day last year.

The new figures show that the number of people estimated to be living with HIV or AIDS include 20.6 million in sub-Saharan Africa, 6 million in South and Southeast Asia and 1.3 million in Latin America and 530,000 in Western Europe.

The worst affected is sub-Sahara Africa where HIV (human immunodeficiency virus) cases increased by an alarming 7.4 percent among people between 15 and 49 years of age.

In contrast the rate of new AIDS cases is expected to drop about 30 percent in Western Europe in 1997, with only Portugal and Greece still showing substantial rises.

And new figures from the United States indicate the rate of AIDS will drop by 11 percent in 1997 after decreasing 6 percent last year.

The survey, however, still pointed to many countries in the world where reporting was faulty or nonexistent, making it unclear how long the new estimates would be valid.

Among the 30 million people currently living with HIV, most of them have no idea they are infected,
particularly in the developing world where the epidemic is concentrated.

HIV testing in many countries is done mostly for purposes of surveillance rather than treatment,
which is scarce. Few people have any hope of treatment, so they feel little incentive to get tested, the
report said.

Southern African continues to be the worst affected area. South Africa estimated 2.4 million of its
citizens were living with HIV. Botswana figures have doubled and Zimbabwe estimates the infection
as high as one in every five adults.

Uganda, the first country in Africa to institute a far-reaching AIDS prevention program, has shown
some results with rates dropping about a fifth in 1997 compared to the previous year, particularly
among younger age groups practicing safer sex.

^REUTERS@

PEDIATRIC LABELING NEW YORK TIMES ARTICLE

Q. Are you concerned about the ethical and health care concerns raised by drug manufacturers regarding the unintended consequences of the Administration's regulation requiring companies to test their products in children before marketing them?

A. Absolutely not. It borders on the unethical not to ensure that physicians and other health care professionals have the information they need to most appropriately prescribe needed medications to our nation's children. Today, countless thousands of children are prescribed medications in the absence of this information. This fact helps explain why national representatives of pediatricians and children's hospitals are so supportive of this regulation.

Follow-up question: There does seem to be a disagreement between the industry and health providers on this issue; aren't you concerned even if just one child is needlessly exposed to clinical trials that might be harmful?

A. What the *New York Times* article did not mention is that the Food and Drug Administration (FDA) Commissioner will have the authority to waive testing requirements if he or she determines they are ethically or medically unsound.

For immediate release
December 1, 1997

CONTACT: Cheryl Cook or
Courtenay Purcell
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The Elizabeth Glaser Pediatric AIDS Foundation
Response to the Pharmaceutical Manufacturers Association (PhRMA)
On Testing Drugs for Safety for Children

In a story in the New York Times yesterday, representatives of pharmaceutical manufacturers argue against the FDA's proposed regulations to require that drugs be tested for safety and dosing for children's use. In that story, these representatives make a number of serious errors, omissions, and misleading statements.

The attached is an effort to correct the record. Today, World AIDS Day, is dedicated to "Giving Children Hope in a World with AIDS." On this day, the drug industry's arguments should not go unchallenged.

The current practice among pharmaceutical manufacturers is not to test drugs on children except in special circumstances. The Pediatric AIDS Foundation believes that presumption should be reversed: Drugs should be tested on children unless there is a reason not to. The proposed FDA regulation would accomplish that goal. The drug industry's arguments are without merit.

MORE

Drug Industry Argument in Story:

Developing drugs for children is too expensive.

Response: This is factually mistaken and morally wrong.

The comments of the head of the drug industry lobby are particularly disturbing. He is quoted as saying that the requirement to test important drugs for safety in children would divert money and resources from "drug research that is more beneficial to the general public."

These comments are a clear example of the problem. The drug industry does not see children as part of the "general public." Sick children and their families would find this research to be extremely beneficial, even if the drug industry does not.

The FDA estimates that the cost of testing drugs for safety in children would be $13 to $21 million per year.

By any estimate--the number of sick children who stay sick, the number who have adverse reactions, the number of needless hospitalizations, or the eight ten thousandths of one percent of the revenues of the top ten pharmaceutical companies--this is a modest amount.

The drug industry itself estimates that the current cost of development of *each* new drug is $500 million. The cost of pediatric trials is almost vanishingly small in this context.

Drug Industry Argument in Story:

The drug industry is primarily concerned about protecting the safety of children and avoiding exposing children to the risks of research.

Response: Children are now placed at significant risk through the industry practice of failure to test drugs. As the American Academy of Pediatrics has noted, the use of untested drugs "may place more children at risk than if drugs were administered as part of well-designed, controlled clinical trials."

Drugs that are untested in children are widely used already. Five million prescriptions a year are written for the top ten unstudied drugs alone. These drugs are administered without adequate testing for safety in children.

Guidelines have been established by both HHS and the American Academy of Pediatrics about the protection of children in research.

The proposed regulation contains a specific waiver if there are grounds to believe that the drug is unsafe in children.

Drug Industry Argument in Story:

The drug industry is primarily concerned about the ethics of testing drugs for safety in children.

Response: No one is more concerned about the ethical treatment of children than children's advocates, such as the Foundation, the American Academy of Pediatrics, the National Association of Children's Hospitals, and the AIDS Policy Center for Children, Youth, and Families. All of these groups support the proposed FDA regulation that the manufacturers are opposing.

The true ethical issue is the drug industry's continued practice of routinely refusing to study drugs for safety in children, even though the industry knows that these drugs are given to children. More children are placed at risk through this practice than would be through well designed and monitored clinical trials.

The HHS and American Academy of Pediatrics' guidelines about the protection of children in research have fully addressed the ethical concerns about how to design safety trials.

Drug Industry Argument in Story: There are practical difficulties in testing drugs for children and in developing formulations appropriate for them.

Response: All drug research has some practical difficulties, not just children's research.

The proposed regulation offers a specific waiver of the children's research requirement if the study is highly impractical and another specific waiver if reasonable efforts to develop a pediatric formulation (when needed) fail.

Drug Industry Argument in Story: Developing special formulations for young children is impractical.

Response: Although industry argues that special formulations are often a problem, this Drug Industry Argument is applicable only to very young children who cannot swallow pills. If problems in formulation were the reason that industry fails to do research on children, one would expect that research on older children would be routinely done. It is not. Manufacturers have largely failed to do research on children under the age of 12, and some have done no research on children under 16.

The proposed regulation offers a specific waiver of the children's research requirement if reasonable efforts to develop a pediatric formulation (when needed) fail.

Drug Industry Argument in Story:
Adult drugs should not be delayed.

Response: Agreed. There should be no delay in drugs for adults. The only action proposed in the regulation if a manufacturer fails to do pediatric research is a court order requiring them to do it, but no delay in approving the drug for adults.

ork Times

Washington Final
Washington and Baltimore: Cloudy, some rain. High in 50's. Tonight, rain ending late. Low near 40. Tomorrow, morning clouds, then windy, brighter. High, 40's. Details are on page 48.

MBER 30, 1997 + *THREE DOLLARS*

Light Trucks Increase Profits But Foul Air More Than Cars

By KEITH BRADSHER

DETROIT, Nov. 29.— After the Chrysler Corporation spent more than half a billion dollars to convert a car factory in Newark, Del., to produce big Dodge Durango sport utility vehicles, it held a party in September to open the new assembly line. Delaware's political leaders stood with Chrysler's chairman on a podium decorated with red and white bunting and waved victoriously to hundreds of cheering auto workers whose jobs had been saved.

When the Durango went on sale this fall, dealers could not keep enough in stock. And Chrysler, which barely breaks even on ordinary passenger cars, began pocketing $8,000 in profit for every Durango sold.

There is just one problem: The Dodge Durango has a much worse environmental record than the

ICENSE TO POLLUTE

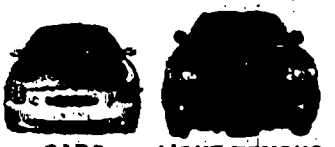
A special report.

Dodge Intrepid, the full-sized sedan hat the factory used to build. The Durango's gasoline consumption and utput of carbon dioxide, a principal ause of global warming, are 57 per-ent higher than those of the Intrep-d. And the Durango's emissions of itrogen oxides, the main cause of nog, are twice the level of the car it placed.

If the Durango and most other ort utility vehicles, pickup trucks nd mini-vans were classified as rs, they would violate Federal andards for pollution and gasoline nsumption aimed at protecting the vironment and conserving energy. stead, these vehicles have long en classified as "light trucks" be-use they were once used mostly on rms and construction sites.

Lawmakers, regulators and Presi-nts back to the Johnson Adminis-ation have granted special favors

Auto makers enjoy rules for light trucks that are less stringent than those for ordinary cars. Light trucks include pickups, mini-vans and sport utility vehicles.



	CARS	LIGHT TRUCKS
GAS MILEAGE		
Minimum average m.p.g.	27.5	20.7*
EMISSIONS (max. per mile)		
Nitrogen oxides (grams)	0.4	0.4–1.1
Carbon dioxide† (lbs.)	0.72	0.95
TAXES		
Gas-guzzler tax	Covered	Exempt
Luxury vehicle tax	Covered	Exempt Larger models

*The very largest models are exempt from gas mileage rules.
†Average emissions, regulated indirectly through gas mileage rules.

The New York Times

family vehicles sold and even though most of them are used by suburban Americans simply for shopping and commuting.

American emissions of global warming gases are increasing even faster than previously expected, in part because of the rise in popularity of sport utility vehicles and other gas-guzzling light trucks. These

PROPOSAL TO TEST DRUGS IN CHILDREN MEETS RESISTANCE

ETHICAL CONCERNS RAISED

Citing Cost and Safety Issues, Makers of Medicines Fight Plan Offered by Clinton

By ROBERT PEAR

WASHINGTON, Nov. 27 — Fierce disputes have erupted over a proposal by President Clinton that would require drug companies to test their products in children before putting new medicines on the market.

Mr. Clinton says such studies will improve health care for children by helping doctors assess the safety and determine the proper doses of drugs that are used to treat children.

But drug companies say the President's proposal will needlessly put thousands of children at risk. And these companies contend that the Government has no legal authority to make them conduct such studies.

When Mr. Clinton announced his proposal on Aug. 13, it seemed politically irresistible. But it is proving much more complicated than expected, and Federal officials now acknowledge that the testing of drugs in children raises ethical questions not found in clinical trials with adults.

Since many important drugs are not tested in children, Mr. Clinton said, doctors must often guess at the appropriate doses, and youngsters may be deprived of "the very best treatment available."

Doctors have generally supported the proposal. Dr. Susan P. Etheridge, a pediatric cardiologist at the University of Utah, said it could be "the

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American emissions of global warming gases are increasing even faster than previously expected, in part because of the rise in popularity of sport utility vehicles and other gas-guzzling light trucks. These trucks will be the fastest-growing source of global warming gases in the United States over the next decade, exceeding the increase in all industrial emissions combined, according to an Environmental Protec-

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vestment Fraud Is Soaring long With the Stock Market

By LESLIE EATON

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York, which is home to
the brokerage "boiler
rooms" that push phony stocks, complaints about brokers jumped 40 percent last year, to 3,100, and are running at an even higher rate this year, said Andrew Kandel, chief of the securities bureau for the State Attorney General, Dennis C. Vacco.

Law enforcement officials are becoming concerned that con men, swindlers and even violent thugs are turning to what they see as easy pickings in the stock market. Last week, the United States Attorney in Manhattan indicted 19 people, including some described as senior members of two of New York's organized crime families, on charges that they defrauded investors in seven states out of millions of dollars.

Wall Street has always had a dark side, and stock swindlers still represent a tiny fraction of the securities industry.

But the size and scope of fraudulent activity appears to be soaring along with the stock market, which has given investors unprecedented

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a Golden Future, All at 13

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said, doctors must often guess at the appropriate doses, and youngsters may be deprived of "the very best treatment available."

Doctors have generally supported the proposal. Dr. Susan P. Etheridge, a pediatric cardiologist at the University of Utah, said it could be "the biggest step forward for drug treatment of children in three decades."

Lawrence A. McAndrews, president of the National Association of Children's Hospitals, said, "Only about 20 percent of drugs marketed in the United States have been tested and labeled specifically for children."

Under the President's proposal, drug makers would have to test their products in children if the drugs were used, or were likely to be used, in "a substantial number of pediatric patients" or if they offered "a meaningful therapeutic benefit over existing treatments" for children.

Dr. Michael A. Friedman, Deputy Commissioner of the Food and Drug Administration, said, "Many drugs labeled only for adult use are, in fact, widely used in pediatric patients" for the same illnesses.

Indeed, doctors say, drugs are routinely prescribed for children even when the labels carry a disclaimer

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TODAY'S SECTIONS

Drug Companies Protest Plan to Test Medicine in Children

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saying, "Safety and effectiveness in pediatric patients have not been established."

Mr. Clinton's proposal would authorize the Food and Drug Administration to seek court orders requiring drug companies to study how their products affect children. Violators would be subject to fines and other penalties.

In proposing the requirements, the F.D.A. said, "History is replete with examples of children who have died or suffered other serious adverse effects as a result of the use of drugs that have not been tested in children."

Alan F. Holmer, president of the Pharmaceutical Research and Manufacturers of America, a lobby for drug companies, said Mr. Clinton's proposals were well-intentioned but could harm children because they would require testing of new chemical compounds in children before the drugs' safety in adults had been adequately studied.

The proposals would impose "new risks on children who might be recruited for clinical trials," Mr. Holmer said. Companies worry that children injured in drug tests might file lawsuits years later, after they grow up, even though parents gave consent for the tests. The tests raise the ethical question of how researchers can obtain informed consent from children as they do from adults.

Drug makers including Merck, Glaxo Wellcome, Novartis and Wyeth-Ayerst said they shared Mr. Clinton's goal of discovering better medicines for children but found the details of his proposal extremely impractical and burdensome.

Mr. Holmer said that a prescription drug should ordinarily not be tested in children until scientists had clear evidence that it was safe and effective for adults. Requiring that drugs be studied simultaneously in children and adults could delay the approval of life-saving medications for adults, he said. Drug company executives said that Mr. Clinton, in his zeal to protect children, was exceeding his authority under Federal law. The job of the F.D.A., they said, is to review drugs for the uses proposed by manufacturers.

The Clinton Administration assumed that the new drug trials would cost an average of $5,000 to $9,000 for each child included in a study. Overall, it said, the proposed rule would impose costs of $13 million to $21 million a year on the drug industry.

But drug companies said the costs would be much higher. Mr. Holmer said the proposal would set "a dangerous precedent," diverting money and other resources away from "drug research that is more beneficial to the general public."

Janne Wissel, vice president of the Alza Corporation, a maker of drug-delivery technology in Palo Alto, Calif., said, "The cost of performing pediatric studies, especially for small companies, may be prohibitive."

Young children often have difficulty swallowing pills, tablets and capsules. So drug companies often need to devise liquid, chewable or injectable forms of their products. Companies say it may cost millions of dollars to develop a formulation specifically for children.

In the absence of such products, parents make their own arrangements, cutting up tablets, crushing them with a mortar and pestle or mixing them with liquid so children can swallow them. But, Dr. Etheridge said, that is "not the most accurate way" to measure out drugs.

Drug companies said that under Mr. Clinton's proposal they would have to conduct separate tests in newborn infants, young children and teen-agers, because children of different ages often reacted differently, requiring different amounts of drug per pound of body weight.

Chris Jennings, a White House aide, said the drug companies' objections were not surprising. "We tried it their way, and it didn't seem to work particularly well," he said, noting prior efforts by the Government to encourage voluntary testing of drugs in children.

Dr. Joseph R. Zanga, president of the American Academy of Pediatrics, supported Mr. Clinton's proposal. Many drugs go on the market with little or no information about their effects on children, he said, so the Government must use its authority to require drug makers to conduct pediatric studies.

But Dr. Bonnie J. Goldmann, vice president of the research laboratories at Merck & Company, said that financial and other incentives would be far more effective than threats of punishment in encouraging studies of drugs for children.

Clinton Seeks to Extend Volunteer Programs

WASHINGTON, Nov. 29 (Reuters) — President Clinton said today that he would seek to extend AmeriCorps and two other national service programs for five more years.

In his weekly radio address, Mr. Clinton stressed the value of citizen service and said he was offering legislation to prolong the life of AmeriCorps — the domestic equivalent of the Peace Corps — and two other volunteer programs, Learn and Serve America and the National Senior Service Corps.

"Citizen service must be at the heart of our efforts to prepare Americans for the 21st century as we work to guarantee all Americans the opportunity and conditions to make the most of their own lives and to help those in need," Mr. Clinton said.

Voluntary service has been a theme of the Clinton Presidency. The AmeriCorps program, which was created in 1993, rewards volunteers with a $4,725 grant to finance their education. So far, more than 100,000 Americans have enrolled in the program.

"AmeriCorps members are mobilizing thousands and thousands of college students from 800 campuses in our America Reads program, to make sure that all our young people can read independently by third grade," Mr. Clinton said.

Map May Renew Dispute Over New England Island