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LOG CABIN EDUCATION FUND

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April 29, 1998

Mr. Richard Socarides
Office of Public Liaison
FAX Transmission

Dear Richard:

I am writing to invite the Administration to send a representative to participate in an HIV/AIDS Congressional Policy Briefing to be held on Capitol Hill on Thursday, May 14, 1998 from 10:00am to 12:00pm, sponsored by the Log Cabin Education Fund through its Free Market Medical Innovation Project. The briefing, entitled "Changing Solutions for a Changing Epidemic," will focus on new developments in HIV/AIDS therapies, the impact of these breakthroughs on the epidemic and implications for current and future public policy. The Honorary Congressional Chairs for the briefing will be Congressman John Porter (R-IL), chairman of the House Labor/HHS Appropriations Subcommittee, and Congresswoman Anna Eshoo (D-CA) of the House Commerce Health and Environment Subcommittee.

The Log Cabin Education Fund is a non-partisan organization which seeks to educate the American people on issues of primary concern to the gay and lesbian community. Development of public policy related to HIV/AIDS are a major part of LCEF's work. The LCEF AIDS Policy Institute focuses on mainstream solutions and policy recommendations in the arena of HIV/AIDS medical care and treatment development, with an emphasis on the free market. The Free Market Medical Innovation Project seeks to educate the public on the array of new HIV/AIDS treatments, and to study the impact of these new treatments on HIV/AIDS medical care policies.

We would be honored if an Administration representative with recognized expertise in HIV/AIDS policy were to give the main presentation at the beginning of the briefing (10-15 minutes) on the state of the AIDS epidemic today, with a ten minute period of questions and answers from the attendees to follow.

We will be following up with your office to discuss the briefing in greater detail and the Administration's possible participation. I look forward to talking with you about it.

Sincerely,

RICHARD TAFEL
President

Kevin Ivers

x12

BRIEFING PROGRAM

Richard L. Tafel, President, LCEF
Moderator

STATE OF THE EPIDEMIC

- 10³⁵ Presentation 1: Mr. Todd Summers
Deputy Director, White House Office of National AIDS Policy
- 10⁴⁵ Presentation 2: *Affected Populations*
Martin Ornelas-Quintero
Executive Director, LLEGO

MEDICAL AND SCIENTIFIC BREAKTHROUGHS

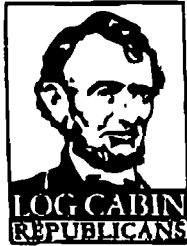
- 11⁰⁰ Presentation: Dr. Anthony Fauci
National Institutes of Health

SOLUTIONS IN ACTION: PATIENTS' PERSPECTIVES

- 11²⁰ Presentation 1: Kenneth W. Lowry
Member, HIV Planning Council of New York
- 11⁴⁰ Presentation 2: Michael Maurer, Ph.D., D. MIN, M.H.A.
Member, HIV Planning Council of Philadelphia

POLICY SOLUTIONS

- 11⁵⁰ Presentation 1: *The Impact of Regulation on Drug Development*
Sam Kazman
Competitive Enterprise Institute
- 12⁰⁰ Presentation 2: *ADAP Success Stories: The New York Example*
Dr. Gus Birkhead
Director, New York State Department of Health AIDS Institute
- 12¹⁰ Presentation 3: *The Role of the Federal Government*
Richard L. Tafel
President, Log Cabin Education Fund
- James Driscoll, Ph.D.
National AIDS Policy Advisor, LCEF AIDS Policy Institute



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Date

5/13

Number of pages including cover sheet

2

TO: Todd Summers

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FROM:

Kevin Owens

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CC:

REMARKS:

☐

Urgent



For your review

☐

Reply ASAP

☐

Please Comment

Please bring slides about ten mins. early so we can load them + test the machine - avoid any problems, etc.

Thanks - and if you'd like any written material (less than 5 pages please) for the briefing packet please messenger/fax by 3pm today - thanks -

If you have problems receiving this document, please call (202) 347-5306 immediately.



LOG CABIN EDUCATION FUND
AIDS POLICY INSTITUTE

Congressional Luncheon Policy Briefing

**AIDS: CHANGING SOLUTIONS
FOR A CHANGING EPIDEMIC**

A program of the Free Market Medical Innovation Project

**Thursday, May 14, 1998
628 Dirksen Senate Office Bldg.**

AIDS: Changing Solutions for a Changing Epidemic

Honorary Congressional Co-Chairs

Congressman John Porter (R-IL)

Chairman, House Appropriations Subcommittee on Labor, HHS and Education

Congresswoman Anna Eshoo (D-CA)

House Commerce Subcommittee on Health and the Environment

Corporate Sponsors of the Free Market Medical Innovation Project

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Moderator**

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Luncheon Will Then Be Served -- Speakers Will Participate In Questions & Answers

AIDS is a bi-partisan issue

By James Driscoll

Nine years ago this week, the Names Project AIDS Memorial Quilt, containing 1,920 panels, was first displayed to honor loved ones lost to this horrible disease. Today, the AIDS Memorial Quilt has grown to more than 40,000 panels and is again on display, this weekend, in our nation's capital. The frustration from which the quilt was born is still evident, but the recent development of life-giving AIDS drugs has brought new hope. These treatment advances, which have significantly extended lives, are the fruits of private sector research, not government efforts.

The frustration that led many to express their pain and suffering through the venerable American tradition of quilting is being replaced by outrage. Many Democratic AIDS activists are exploiting human suffering with partisan politics by falsifying the Republican record and diminishing private-sector accomplishments in order to promote Bill Clinton.

In 1994, when Republicans won both houses of Congress, the Ryan White CARE Act, the federal government's AIDS care and treatment program, was facing reauthorization. Many Democrat activists insisted that the Republican-controlled Congress would be "devastating," "draconian" and would "eviscerate" all AIDS programs.

The Republican-controlled 104th Congress did have its plate full during the first 100 days with the Contract With America. However, they demonstrated concern and understanding of AIDS issues when the House held hearings on the reauthorization of Ryan White during those first 100 days. This was something left-wing AIDS activists promised would never happen. Indeed, under the Democratic-controlled Congress, no Ryan White

hearings occurred.

The GOP Congress reauthorized Ryan White; readjusted the program's formulas, making them more equitable; and this year alone, they increased Ryan White funding by 30 percent. Moreover, Republican regulatory reform efforts pressured the Food and Drug Administration to speed approval of the new AIDS drugs, thus saving thousands of lives sooner.

Astonishingly, many AIDS activists tried to give the Clinton administration all the credit for the Ryan White reauthorization and funding increases. At the same time, they ignored the beneficial impact of GOP congress-



sional oversight on FDA.

As Bob Dole explained in last Sunday's debate, Mr. Clinton has a photo-op foreign policy. Similarly, in the area of AIDS, his accomplishments are limited to photo-op appearances, such as co-chairing this weekend's quilt display and last December's "AIDS Summit." This event was loaded with high-dollar donors to the Democratic Party while top AIDS experts, who happen to be Republican, were excluded.

However, only two weeks ago, he showed his true colors when he opposed adequate funding for the crucial AIDS Drugs Assistance Program (ADAP), which provides the new treatment advances to uninsured patients.

The 1997 appropriations process clearly reveals Mr. Clinton's defective leadership on AIDS funding. Rep. John Porter, Chairman of the Labor and Health and Human Services Appropriations committee, led the

drive to provide more access to the new drugs, thereby lessening the need of people living with AIDS to go on Medicaid. Mr. Clinton, however, would not request the additional funding, and left Mr. Porter's committee to assemble the increase on their own.

Mr. Porter said that "despite tight budgetary circumstances, and a lack of support from the Clinton administration for increased funding, I'm pleased that Congress was able to find a way to provide this additional \$100 million in Ryan White funding." In fact, Rep. Nancy Pelosi, who carried the ball for the Democrats on pushing for the increase, was tackled by her own AIDS activist constituents who demanded half of the money for their own AIDS infrastructure in San Francisco.

The Human Rights Campaign, a gay political organization that has endorsed and contributed millions to Mr. Clinton's re-election campaign, claimed the "administration squeezed out extra funding for AIDS." This fabrication underscores what's wrong in AIDS politics today. We need bipartisan leadership, and bipartisan solutions. The Republicans deserve credit where it is due on AIDS, and the White House must provide much more effective leadership.

In truth, a few Republican loose cannons have damaged the image of the 104th Congress on AIDS, most notably Rep. Bob Dornan, whose mischief on HIV in the military had to be reversed by fellow Republicans, such as Rep. Peter Torkildsen and Sen. John McCain. But overall, the 104th Congress has delivered for people with AIDS.

As we turn the corner on the AIDS epidemic, which has taken more than 320,000 American lives, this weekend's viewing of the memorial quilt will again remind us of the courage, suffering and love expressed in each panel. In mourning those we have lost, let's be honest about the records of both parties in the fight against AIDS. Hope can only flourish when both ends of Pennsylvania Avenue are full partners in the solution.

James Driscoll, an AIDS activist, is the national AIDS policy advisor to the Log Cabin Republicans.

FEDERAL AIDS PROGRAMS: FUNDING NEEDS FOR FY99

FEDERAL PROGRAM	FY 98 Appropriation	FY 99 President's Request	FY 99 Need
Centers for Disease Control and Prevention: HIV Prevention	\$634.3	\$632.3 (-\$2)	\$819.3 (+\$185)
Health Research and Services Administration: Ryan White CARE Act, Total	\$1,150.2	\$1,315.2 (+\$165)	\$1,578.1 (+\$427.9)
Title I	\$464.8	\$489.8 (+\$25)	\$570 (+\$105.2)
Title II: Care Services	\$257.5	\$284.5 (+\$27)	\$342.5 (+\$85)
Title II: AIDS Drug Assistance Program	\$285.5	\$385.5 (+\$100)	\$458.5 (+\$173)
Title III	\$76.3	\$86.3 (+\$10)	\$113 (+\$36.7)
Title IV	\$41	\$44 (+\$3)	\$61 (+\$20)
Title V: AIDS Education and Training Centers	\$17.3	\$17.3 (+\$0)	\$25.0 (+\$7.7)
Title V: Dental Reimbursement	\$7.8	\$7.8 (+\$0)	\$9 (+\$1.2)
National Institutes of Health: HIV/AIDS Research	\$1,608	\$1,732 (+\$124)	\$1,848 (+\$241)
Housing Opportunities for People with AIDS	\$204	\$225 (+\$21)	\$250 (+\$46)
Substance Abuse Prevention & Treatment Blockgrant	\$1,310	\$1,510 (+\$200)	\$1,510 (+\$200)

All numbers are in millions. FY 98 figures are from FY 98 appropriations bills signed into law in Oct. and Nov. 1997. Need figures are supported by the National Organizations Responding to AIDS coalition.

*Funding for
youth specifically
School-based
programs
STDs*



The National Latina/o
Lesbian, Gay, Bisexual
& Transgender Organization

HIV/AIDS in the Latina/o LGBT Community in the United States

According to the Centers for Disease Control and Prevention's HIV/AIDS Surveillance Report, the ten states in the country with the highest number of reported HIV/AIDS cases are California, Florida, Georgia, Illinois, Maryland, New Jersey, New York, Pennsylvania and Virginia¹. To these we should add the Commonwealth of Puerto Rico and the District of Columbia. If one were to closely examine this listing, one would note that it is in these states where one finds the highest concentration of Latinas/os. These states and territories have a total of 468,341 reported cases, which represents almost 77% of all reported cases².

In a sampling of the 20 states and territories with the highest concentration of Latinas/os³, the results are equally alarming. These cases have 78% of all reported cases⁴. Of these cases, 98,427 are Latinas/os—almost 25%.

It is important to note the fact that of the reported cases of HIV/AIDS in the Latina/o community, 41% are men who have sex with men or men who have sex with men while using drugs⁵. This means that almost half of all cases are reported are gay and bisexual Latino men. However, the disbursement of funds directed to this specific population is nowhere in proportion to this fact.

One should notice that high-risk categories were not disclosed at the moment of diagnosis in 28% of new cases of HIV and 20% of new cases of AIDS. It is important to add that given the fact that neither race nor ethnic origins are in and of themselves risk factors, it does present factors that are linked to high-risk behavior and factors that can help in the design of more effective prevention programs. When making this analysis, one must also take into account the role of homophobia in the Latina/o community and its influence in the lack of prevention. Internalized homophobia impedes the identification of Latinas/os as gay,

¹ Centers for Disease Control and Prevention, *HIV/AIDS Surveillance Report*, Midyear Edition, Vol. 9, No. 1, June '97, page 5.

² 76.516%.

³ Arizona, California, Connecticut, Colorado, Florida, Kansas, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Texas, Utah, Washington, Puerto Rico and the District of Columbia.

⁴ 78.47%.

⁵ Data from the University of California, San Francisco.

lesbians or bisexuals. This makes for more difficulties in designing prevention education programs, since consumers do not identify their true risk-exposure category. This is demonstrated by the statistics at the beginning of this paragraph⁶.

On the other hand, the fact that the 14% of the new HIV/AIDS reported cases are patients between 13 - 24 years old tells us that prevention efforts targeting this group have not been effective. Among Latinas/os we know that homophobia impedes young people from expressing their sexual preferences. That necessitates the creation of safe environments and prevention programs culturally appropriate to our ethnic heritage.

Out of a sampling of 25 states used by The Centers for Diseases Control and Prevention, the largest percent increase of HIV/AIDS cases was in the Latina/o community (10%). What is not defined in this study is how many of those cases are under the exposure categories of men who have sex with men and/or use drugs. Because most patients do not disclose their risk-exposure category when diagnosed, it is also true that in the Latina/o community it is much harder to identify these categories due to homophobia.

To summarize, HIV/AIDS figures continue to rise in the Latina/o community. These figures are considerably higher in the gay/lesbian/bisexual community than in any other of the high risk-exposure categories. However, prevention funding for this category is not proportional. Even though it is true that a percentage of new reported cases do not identify their exposure category, we do know that, at least in the Latino community, this is due to internalized homophobia. These are factors that must be considered when designing prevention programs targeting the Latina/o community. Therefore, it is important that prevention programs for the Latina/o community be created and developed by Latinas/os, thereby assuring the inclusiveness of members of this community.

⁶ Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Vol. 47, No. 15, April 24, '98, page 311.

Characteristic	Disease status at initial HIV diagnosis				Total
	HIV		AIDS		
	No. [‡]	(%) [§]	No. [‡]	(%) [§]	
Sex					54,862
Male	37,996	(72)	16,866	(83)	18,037
Female	14,689	(28)	3,348	(17)	
Race/Ethnicity**					27,100
White, non-Hispanic	17,929	(34)	9,171	(45)	39,356
Black, non-Hispanic	30,229	(57)	9,127	(45)	5,241
Hispanic	3,581	(7)	1,660	(8)	1,205
Other/Unknown	949	(2)	256	(1)	
Risk/Exposure category					25,964
Men having sex with men	17,098	(32)	8,866	(44)	13,630
Injecting-drug user	9,671	(18)	3,959	(20)	
Men having sex with men/ Injecting-drug user	2,088	(4)	843	(4)	2,931
Heterosexual contact	9,279	(18)	2,428	(12)	11,707
Other/Unreported	14,552	(28)	4,116	(20)	18,668
Age group (yrs)					7,853
13-24	7,200	(14)	653	(3)	11,623
25-29	9,384	(18)	2,239	(11)	16,419
30-34	11,916	(23)	4,503	(22)	14,638
35-39	10,030	(19)	4,608	(23)	22,369
≥40	14,159	(27)	8,210	(41)	
Total ^{††}	52,690		20,215		72,905

* For persons who had not had an HIV diagnosis before being diagnosed with AIDS, their AIDS diagnosis date is considered their earliest HIV diagnosis date; for persons initially reported with HIV who subsequently had AIDS diagnosed and reported, they are presented by the earliest diagnosis date, which is their HIV diagnosis.

† Alabama, Arizona, Arkansas, Colorado, Idaho, Indiana, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, Wisconsin, and Wyoming.

‡ Numbers are estimates after adjustments for reporting delays. Point estimates are presented for reproducibility of the data.

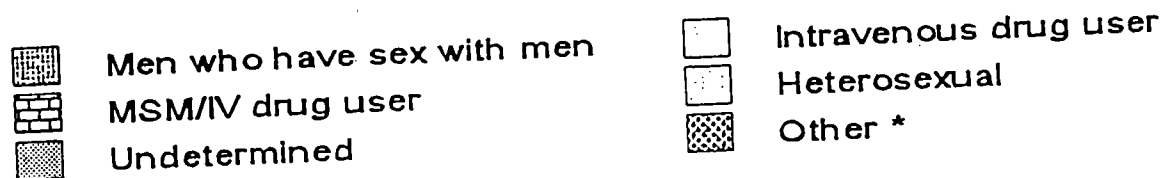
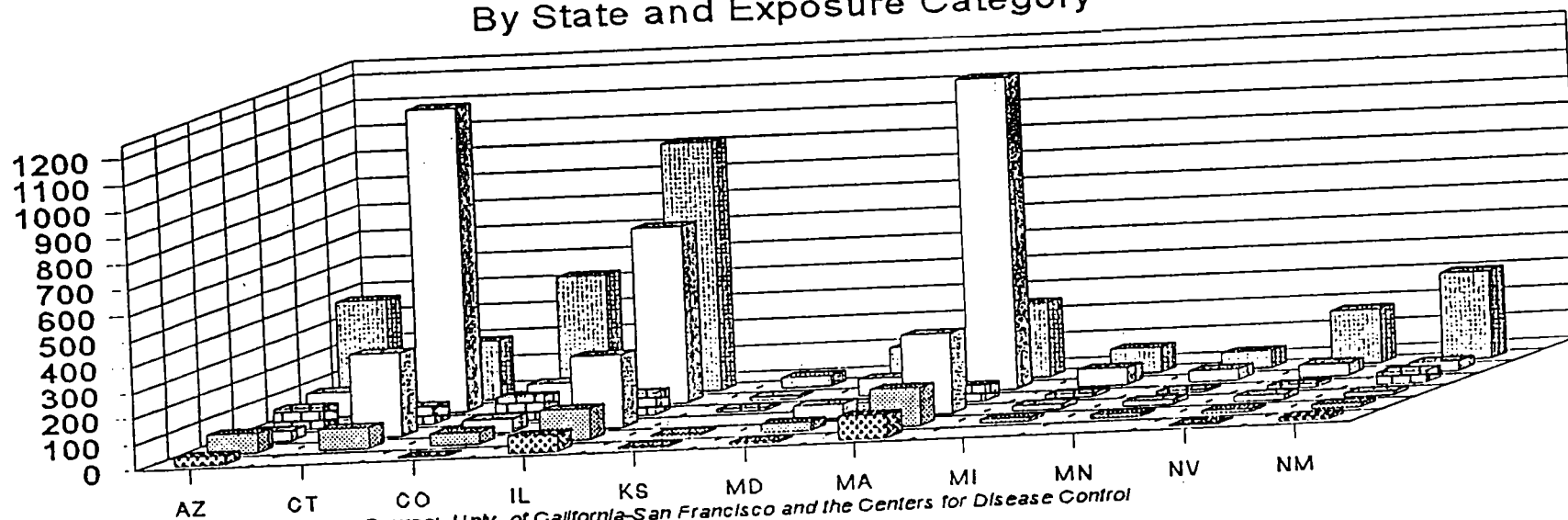
§ Percentages may not total 100 because of rounding.

** Persons of races other than black and white were included under "other/unknown" because estimates were too small for meaningful analysis.

†† Column totals include missing/other for some categories (e.g., missing sex). Persons infected through receipt of blood or blood products are included under other/unreported risk.

Latina/o AIDS Cases I

By State and Exposure Category



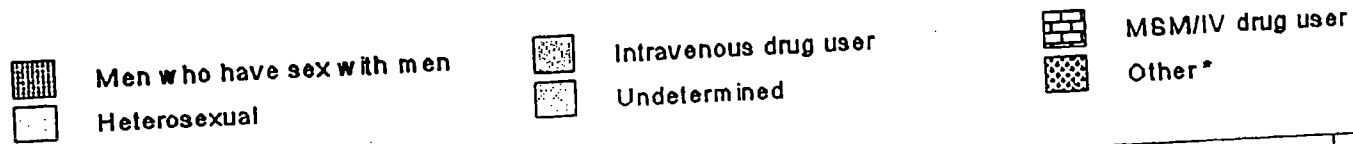
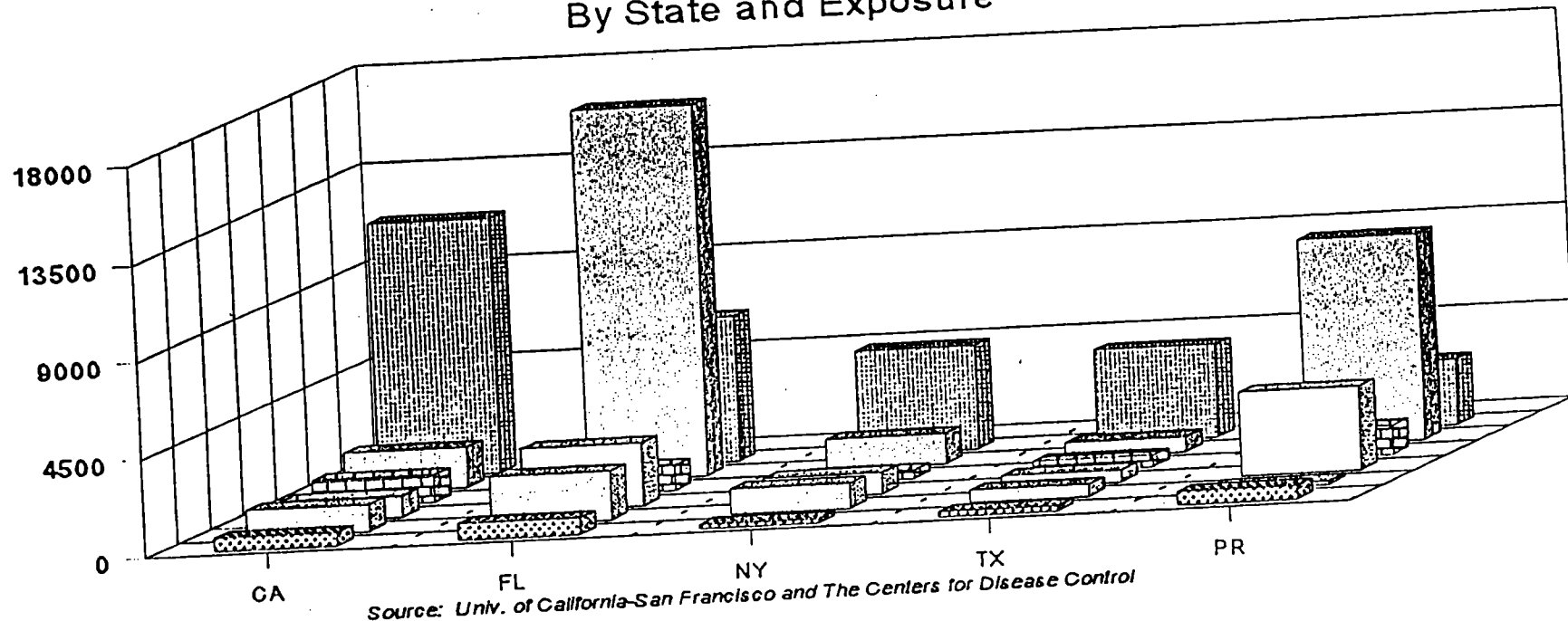
	Arizona	Conne	Colora	Illinois	Kansas	Maryla	Massa	Michlg	Minnes	Nevad	New M
Men w	402	227	465	957	43	138	286	99	67	209	336
Intrave	96	1168	98	681	12	65	1201	67	43	48	37
MSM/I	81	69	91	85	11	11	61	15	10	15	47
Hetero	38	322	50	282		55	311	18	17	21	13
Undete	74	80	46	118	7	31	147	13	13	11	16
Other *	34		4	67	7	9	89			5	15

* Hemophiliacs, blood transfusions, tissue transplants and mother/child transmission.

LLEGÓ - The National Latina/o Lesbian, Gay, Bisexual & Transgender Organization

Latina/o AIDS Cases II

By State and Exposure



	California	Florida	New York	Texas	Puerto Rico
Men who have sex with men	11778	6660	4799	4310	3039
Intravenous drug user	1832	17129	1381	673	9547
MSM/IV drug user	1242	1135	395	512	1306
Heterosexual	954	2853	969	528	3832
Undetermined	1249	2254	1153	572	163
Other*	609	774	209	241	611

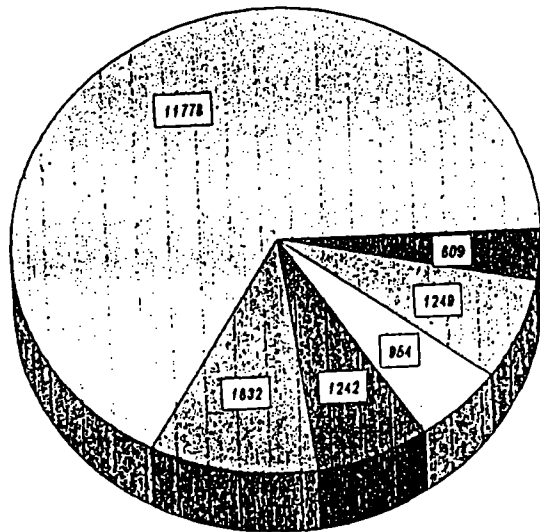
*Hemophiliacs, blood transfusions, tissue transplants and mother/child transmission.

LLEGÓ - The National Latina/o Lesbian, Gay, Bisexual & Transgender Organization

Source: Univ. of California-San Francisco and The Centers for Disease Control

California

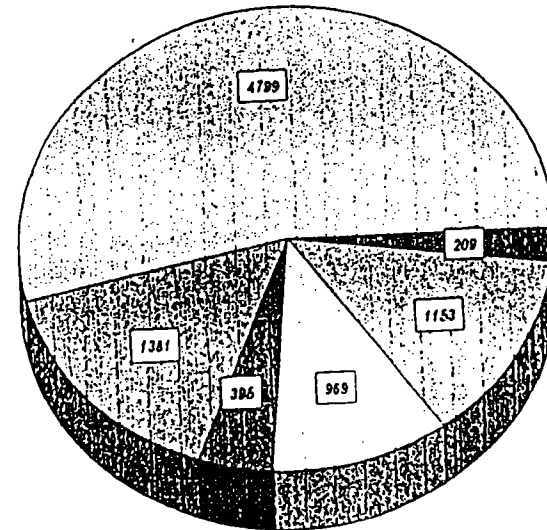
Latina/o HIV/AIDS by Exposure Category



Men who have sex with men
 Heterosexual
 Intravenous drug user
 Undetermined
 MSM/IV drug user
 Other*

New York

Latina/o HIV/AIDS by Exposure Category



Men who have sex with men
 Heterosexual
 Intravenous drug user
 Undetermined
 MSM/IV drug user
 Other*

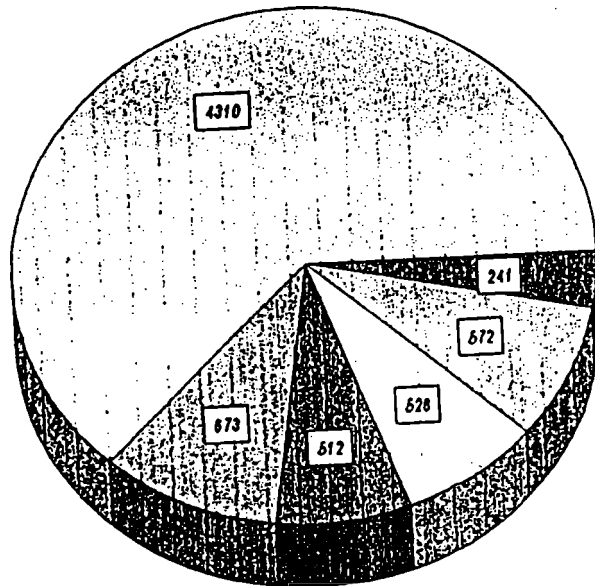
*Hemophiliacs, blood transfusions, tissue transplants and mother/child transmission

LLEGÓ - The National latina/o Lesbian, Gay, Bisexual & Transgender Organization

Source: Univ. Of California-San Francisco and The Centers for Disease Control

Texas

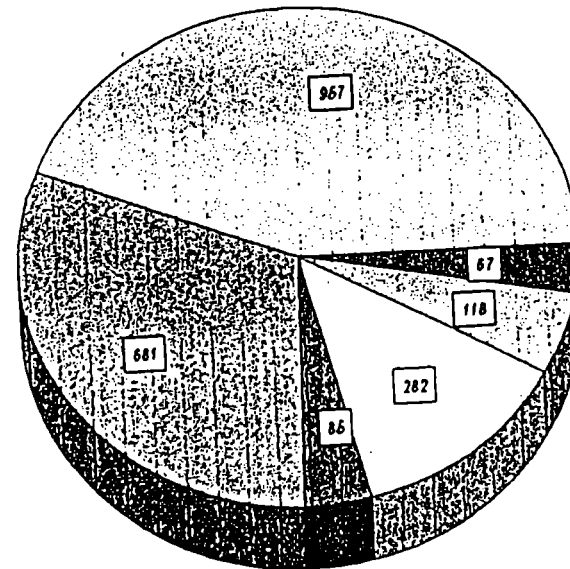
Latina/o HIV/AIDS by Exposure Category



☐ Men who have sex with men
☐ Heterosexual
☐ Intravenous drug user
☐ Undetermined
☐ MSM/IV drug user
☐ Other*

Illinois

Latina/o HIV/AIDS by Exposure Category



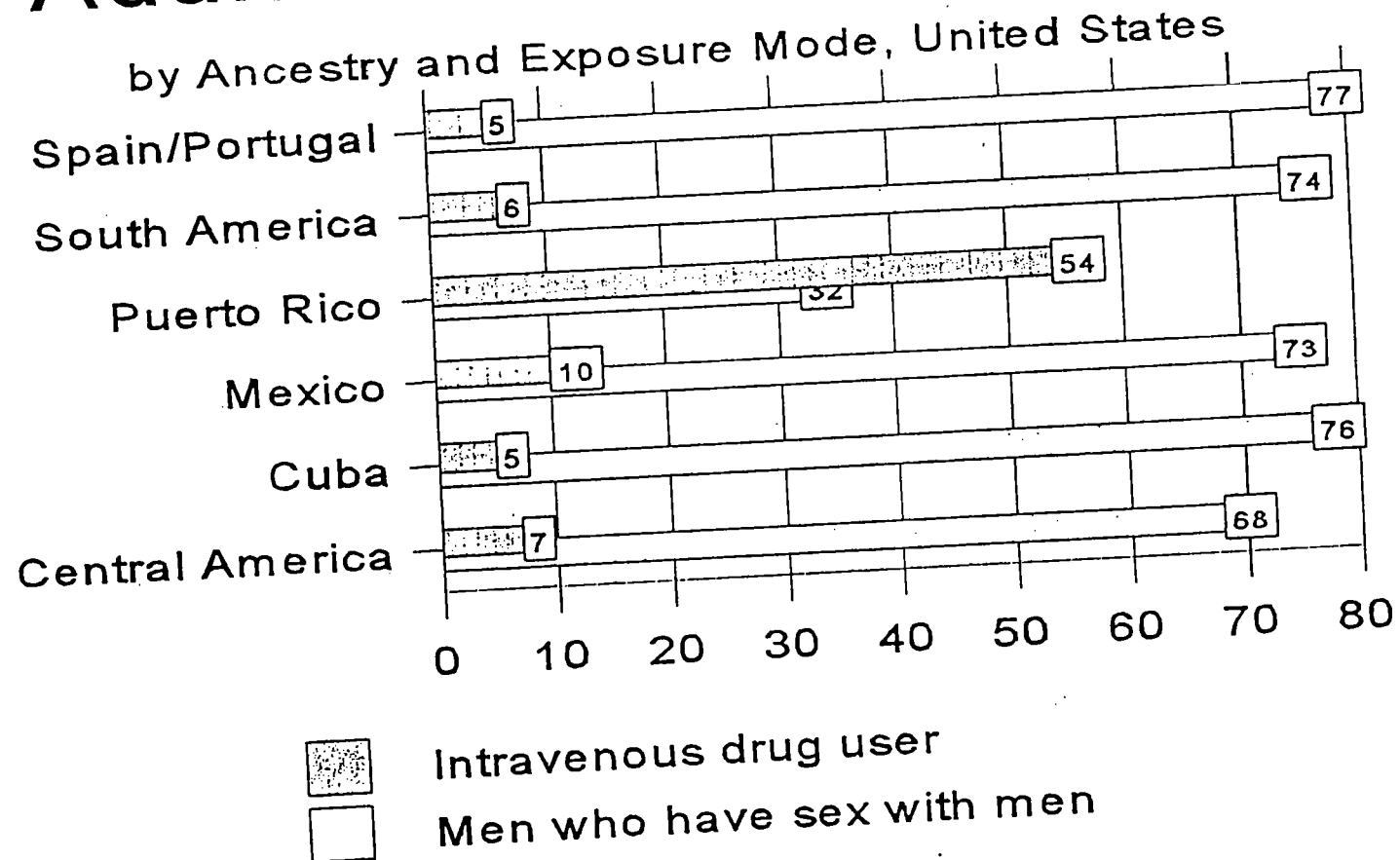
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LLÉGÓ - The National latina/o Lesbian, Gay, Bisexual & Transgender Organizaion

Source: Díaz, Kleven, et.al., *Differences by Ancestry in Sociodemographics and Risk Behaviors among Latinos with AIDS, Ethnicity & Disease, Vol. 7, 1997.*

Adult/Adolescent Hispanic



LLEGÓ - The National Latina/o Lesbian, Gay, Bisexual & Transgender Organization

Psychology & AIDS Exchange

AIDS Resource Network
Office on AIDS



AMERICAN
PSYCHOLOGICAL
ASSOCIATION

Summer 1996
Issue 21

Research News for the Practitioner

LATINO GAY/BISEXUAL MEN: PSYCHO-CULTURAL BARRIERS TO SAFER SEX PRACTICES

As we move through the second decade of the HIV epidemic, the number of diagnosed AIDS cases among Latino gay/bisexual men in the United States continues to increase at a fast and disproportionate rate. By March 1993, a total of 21,021 AIDS cases had been diagnosed in Latino men who have sex with men (MSM; CDC, 1993). By June 1994, 15 months later, the number of diagnosed Latino MSM AIDS cases had risen to 29,432. In this 15-month period, AIDS diagnosed cases increased 40 percent among Latino gay/bisexual men, in contrast to a slower—though also painfully dramatic—29 percent increase in non-Latino White MSM during the same time period. The numbers are even more striking when they are examined for cities with a high concentration of Latinos and homosexuals. In San Francisco, for example, between 1989 and 1992, the number of yearly reported AIDS cases in the city increased 99 percent for Latinos, while only 46 percent for non-Latino Whites; for both ethnic groups, about 80 percent of these cases were among gay/bisexual men.

In line with epidemiological findings, behavioral studies have shown that Latino gay/bisexual men have had enormous difficulties adjusting to condom use and adopting less risky forms of sexual behavior. In fact, five studies that measured rates of risky sexual behavior in gay/bisexual men (Doll, et al, 1991; Fairbank, Bregman & Maullin, 1991; Lemp et al, 1993; NTFAP, 1993; Richwald et al, 1988) have found that Latinos had the highest rates of unprotected anal intercourse when compared to samples of non-Latino Whites, African-Americans, or men from other minority groups. Among Latino gay/bisexual men, the percentage of men who practice unprotected anal intercourse varies according to the window of time observed, from 23-35 percent (within one month) to about 40 percent (within six months) and about 50 percent (within a year). High rates of unprotected anal intercourse co-exist with a high degree of knowledge about HIV transmission and prevention, and the presence of relatively

strong personal intentions to practice safer sex (see Diaz, 1995 for a review of behavioral literature).

BARRIERS AS INTERNALIZED SOCIOCULTURAL FACTORS

In order to understand the factors that compete with the practice of safer sex in this population, I interviewed approximately 62 Latino gay/bisexual men in San Francisco during the period of November 1992 through June 1993; 53 men were interviewed in the context of 10 focus groups and nine men were interviewed through individual in-depth interviews. The men were recruited through establishments, organizations, agencies and friendship networks, ensuring that both Spanish-speaking, non-aculturated men and English-speaking, acculturated men were included. Focus groups and interviews were conducted in either Spanish or English, as appropriate. Approximately half of the sample was Mexican or of Mexican descent; the rest of the sample included eight different nationalities from the Caribbean, Central and South America. One focus group was done with five "Vestidas" ("the ones who dress-up", feminine ending -as), which is the collective name for transvestite/

Latino Gay/Bisexual Men, continued to page 7

INSIDE...

- 2 Office on AIDS Bulletin Board—WANTED: Behavioral Scientists to Become Involved in the CDC Community Planning Process
- 3 Washington News—APA AIDS Advocacy Focuses on Medicaid Proposal and OAR
- 5 From the Chair—Protease Inhibitors—Multiple Dilemmas
- 6 HOPE Program Update—Consumer Approach to Graduate Education About HIV/AIDS
- 12 Give & Take

Latino Gay/Bisexual Men, continued from page 1

transgender persons within the non-acculturated Latino gay/bisexual community. Another focus group included five men who had worked for some time with other gay/bisexual men as health educators and outreach workers within Latino-identified AIDS education/prevention programs in San Francisco.

Focus group and interview questions were formulated to elicit the subjective experiences of Latino gay/bisexual men regarding their developmental and social histories as self-identified gay/bisexual men in Latino communities; their past and current sexual behavior; their perceptions of risk for AIDS infection; their level of commitment to practice safer sex; the perceived difficulties and barriers to safer sex practices; and the major sources of social support, including the relationships to their own families and friends, to the Latino community and to the mainstream gay community in San Francisco.

As expected, men in San Francisco showed a high degree of knowledge about HIV/AIDS, accurate perceptions of risk, and a strong desire to protect themselves and their loved ones and remain healthy. However, in the presence of substantial knowledge, accurate risk perceptions and positive intentions, the men reported multiple incidents of risky behavior in risky situations, including multiple partners, prostitution, sex in public environments, the use of intoxicants during sexual activity and instances of unprotected anal intercourse.

The most striking element of the focus group and in-depth interview data, however, was the parallel found between men's experiences growing up as self-identified but closeted homosexuals in the context of their Latino families on one hand, and the expressed difficulties in the practice of safer sex, on the other. There were some striking "congruences" and meaningful relationships between the

answers given for the following two seemingly unrelated questions: "What is it like to be a Latino gay/bisexual man?" and "What is the most difficult aspect of practicing safer sex?"

For example, in response to the first question, men spoke of the painful doubts about their masculinity during childhood, doubts raised by a societal context where homosexuality is defined as a "gender" problem (i.e., homosexual men are defined as women in men's bodies or as not being "real" men) rather than sexual orientation. Men talked about the need to prove their masculinity in order to feel accepted by other boys and to participate in an often cruel peer culture. In parallel fashion, in response to the second question, men talked about the fear of losing their erections when using condoms and appearing less than manly or like a "loca" (cultural equivalent of "queen"). Men often described sexual encounters as events where they could show their masculinity or experience the masculinity of their partners through dominant, strong, penetrative practices. For many of these men, through important developmental experiences, sexuality has been constructed as a place to create and restore a sense of masculinity and macho ideal. Thus, an extreme focus on penetration and fear of losing erections, identified as major barriers to safer sex, became clearly meaningful within the sociocultural context of machismo for those men who experience same-sex desires within Latino communities.

Similar parallels between internalized sociocultural values and high-risk practices were found for other identified risk factors. For example, there was a clear and meaningful connection between the fact that family acceptance of homosexuality all too often can be achieved only through silence ("They know but we can't talk about it"), and the problems men had in talking about sexuality or negotiating safer sex. The strong and prevalent perception that homosexuality "hurts my family" was closely related to a sense of sexual shame

and a separation of sexuality from social/interpersonal/affective life as manifested by frequent sexual activity within the context of illicit, hidden encounters with strangers in public cruising environments.

The focus group and individual interview data showed that, among the majority of Latino gay/bisexual men interviewed, unsafe practices were not the product of a "deficit" in AIDS knowledge, motivation or skills. Rather, important sociocultural factors and values (by now internalized through socialization practices and currently reinforced by participation in Latino communities and family life) strongly compete with the enactment of safer sex intentions.

Outline For A Psycho-Cultural Model Of HIV Risk

Based on the San Francisco findings, I have outlined below a set of barriers or competing factors to the enactment of safer sex intentions. The barriers are listed under six different headings, with the assumption that they are expressions of six internalized sociocultural factors in the lives of Latino gay/bisexual men in the United States. The outline is offered as a culturally-appropriate model of HIV risk for this vulnerable group of men, where sexual risk behavior is not treated as isolated risk-taking by individuals but rather as sexual expression that has logic and meaning from a given sociocultural perspective.

The label psycho-cultural underscores the fact that, in human development, cultural sexual mores become internalized and give shape to individual's construction of personal values, perceptions and meanings regarding sexuality. Cultural guidelines and proscriptions that regulate sexual behavior in the social group (such as what constitutes appropriate and valued male sexual behavior) become transferred or internalized as personal values, expectations and cognitive scripts that regulate individual sexual behavior. Thus, the barriers to safer practices listed

below are seen not as personal deficits or shortcomings, but rather as logical outcomes of socialization processes manifested in the sexual lives of Latino gay/bisexual men.

The six sociocultural factors and their impact as barriers to HIV prevention vary across groups and individuals in this population. However, a discussion of variability and diversity within the Latino gay/bisexual population is beyond the scope of this writing. Also, the

barriers stated above we offered as hypotheses that must be tested with further research in order to quantitatively assess their impact on reported risk behavior and their generalizability to different groups and individuals. Above all, we should not forget that our quantitative data do suggest that about 50 percent of Latino gay/bisexual men in the U.S. show no evidence of behavior that promotes HIV transmission.

IN CONCLUSION

In this writing I have offered a cultural analysis of risky sexual practices among Latino gay/bisexual men. As a Latino gay man who lives in a highly-affected community, I must strongly state the fact that we do not have time to wait for major societal/cultural changes in order to implement aggressive HIV-prevention programs. The proposed psycho-cultural model

Latino Gay/Bisexual Men, continued to page 9

BARRIERS TO SAFER SEX

1) Machismo

- ▶ An extreme and almost exclusive focus on penetrative sexual practices to the extent that sex without penetration is not considered sex;
- ▶ Perceptions of low sexual control, where a state of high sexual arousal ("estar caliente"; "being hot") is used as a socially-accepted justification for unprotected sex and the surrender of reflective/regulatory control in sexual encounters;
- ▶ A perception of sexuality as a favored place to prove masculinity, where the possibility of losing penis erection is avoided at all costs.

2) Homophobia

- ▶ A strong sense of personal shame about same-sex sexual desire, so much so that fear of rejection in sexual encounters takes precedence over health concerns;
- ▶ Serious problems in self-identification as a member of a group at risk, with consequent denial of personal vulnerability to HIV;
- ▶ Feelings of anxiety about same-sex sexual encounters, leading to an increased use of alcohol, drugs and/or other intoxicants in preparation for sexual activity.

3) Family Cohesion (in the context of close personal involvement with homophobic families)

- ▶ Closeted lives with low levels of identification with and/or social support from a peer gay community;
- ▶ Minimal influence of normative changes in the gay community on sexual behavior because families are seen as the main social-referent group;
- ▶ A forced separation between sexuality and social/affective life or relationships that promotes anonymous, hidden encounters in public cruising places.

4) Sexual Silence

- ▶ Problems in talking openly about sexuality, resulting in difficulties with sexual communication or safer sex negotiation in sexual encounters;
- ▶ Increased sexual discomfort with all matters pertinent to sexuality;
- ▶ The psychological dissociation of sexual thoughts and feelings, decreasing the likelihood of accurate self-observation within the domain of sexuality.

5) Poverty

- ▶ Decreased sense of personal control over one's life, leading to fatalistic notions regarding health and personal well-being;
- ▶ Increased unemployment, drug abuse and violence, undermining the consideration of HIV infection as a major, central or priority concern;
- ▶ Situations of financial dependence such as living with families, exploitative relations with older men, and/or prostitution where the personal power for self-determination and self-regulation is seriously undermined.

6) Racism

- ▶ Increased personal shame about being Latino, with serious negative consequences on self-esteem and personal identity;
- ▶ Lack of participation in the mainstream gay community and its activities. Racist and classist values regarding personal looks, financial power, and educational achievement, highly prevalent in the mostly White and middle-class gay community, conspire against feelings of belonging and social recognition for gay men of color;
- ▶ Racist stereotypes about Latino men as being "passionate, dark and exotic," creating pressure from non-Latino White gay men to practice risky sex.

emphasizes not only the cultural factors but their internalization and impact on individuals sexual lives. We must address, therefore, both the cultural sources of oppression as well as their impact on individual lives.

In the midst of the six-fold oppressive context, prevention efforts can and should facilitate communication, self-observation and critical reflection about the oppressive forces that regulate our sexuality and collaborate with the construction of personal strategies to deal effectively with the barriers to safer sex practices. I have argued that effective prevention programs can be productive with this population if they: 1) break the sexual silence by providing safe venues for serious communication about our sexuality; 2) provide opportunities for critical self-reflection and self-observation about the factors that regulate our sexual behavior; 3) provide an experience of communality and pride, where men can feel part of a supportive and proud Latino gay/bisexual community; and 4) create opportunities for social activism against the sociocultural and socioeconomic forces that undermine our self-determination and sexual self-

regulation. An example of such a program can be seen in the Center for AIDS Prevention Studies/University of California at San Francisco (CAPS/UCSF) home page (<http://www.caps.ucsf.edu/capsweb>) under the heading *Hermanos de Luna y Sol*.

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Consumer Approach continued from page 6

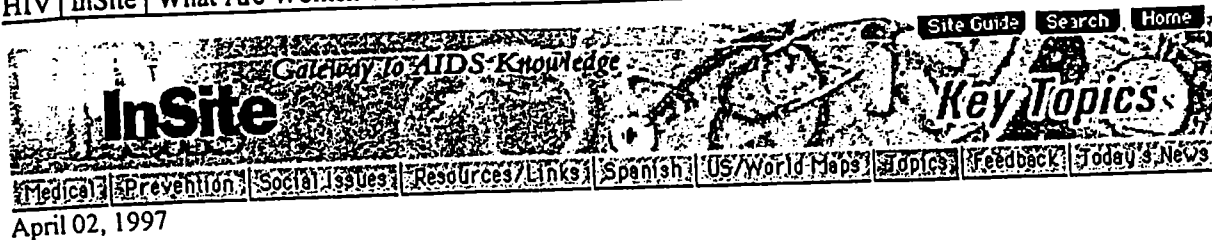
Teaching points based on Dr. Kain's book will provide graduate faculty with key concepts in clinical issues and psychotherapeutic interventions for people infected with and affected by HIV/AIDS. Teaching points based on Dr. Kalichman's book will provide readers with a thorough grounding in empirical work on behavioral and social science aspects of HIV/AIDS. Drs. Kalichman and Kuin will be working with the APA Office on AIDS to ensure that teaching points are integrated with content from other sources and organized in terms of both commonly taught courses (e.g., assessment, human sexuality, ethics, family therapy, etc.) and major fields of psychology (e.g., clinical, community, social, developmental, health, etc.).

Outreach to Psychology Faculty Planned

In the upcoming months, the Office on AIDS plans to conduct a systematic outreach to psychology faculty currently involved with graduate education about HIV/AIDS. The goal of this outreach effort is to involve faculty in the process of developing and sharing resources and strategies for educating graduate students. Our first major networking initiative for faculty interested in graduate education about HIV/AIDS will be held in the Public Interest Suite, at the Sheraton Centre, Toronto, Canadian Room 415, during the APA Convention this summer in Toronto. This networking session, scheduled from 3:30 p.m. to 5:00 p.m. on Saturday August 10th, will provide faculty with an opportunity to make connections, share ideas and exchange resources.

The urgency and magnitude of the HIV pandemic requires that psychology mobilize on a profession-wide scale to provide mental health services to those affected by HIV and to more rapidly test models that show promise for behavior change promotion. Unfortunately, numerous surveys and anecdotal reports suggest that graduate training in psychology has changed very little in response to the epidemic and thus systematic graduate-level education directed toward training students about applying psychological expertise to the challenges of the HIV/AIDS epidemic continues to be relatively rare. The Office on AIDS is committed to changing that situation and we need your help.

*Submitted by John R. Anderson, PhD
Director, Office on AIDS*



What Are Women Who Have Sex with Women's HIV Prevention Needs? ^{NEW}

Provided by Center for AIDS Prevention Studies, UCSF, 1/96

Are women who have sex with women at risk for HIV?

HIV risk for women who have sex with women (WSW), like for all people, varies depending on what they do. Some WSW may shoot drugs, have sex with men, trade sex for money or drugs, be victims of rape or abuse, have sex with many partners or have artificial insemination.

It is important to remember that sexual identity and sexual behavior are not always similar; for example, women who identify as lesbian can also have sex with men, and not all WSW identify as lesbian or bisexual. In this fact sheet, the term "WSW" will cover all these categories, unless a more specific term or definition is offered.

Among injection drug users, WSW have higher HIV rates than do women who have sex with men only. A study of female injection drug users (IDUs) in 14 US cities found that, compared to heterosexual women, women who had a female sex partner were more likely to share syringes, to exchange sex for drugs or money, to be homeless and to seroconvert.⁽¹⁾

Women who identify as lesbian or bisexual and have sex with men may be at high risk for HIV due to male partnering choices and low condom use. A study of lesbians and bisexual women in San Francisco, CA, found that 81% reported sex with men in the past 3 years. Of those women, 39% reported unprotected vaginal sex and 11% unprotected anal sex.⁽²⁾ In a survey of lesbians and bisexual women in 16 small US cities, among women who were currently sexually active with a male partner, 39% reported sex with a gay/bisexual man and 20% sex with an IDU.⁽³⁾

Is female-to-female transmission possible?

From all we know, there is a small but still unspecified risk of HIV transmission associated with female-to-female sexual practices.⁽⁴⁾ HIV is found in vaginal fluids and menstrual blood, but the amount of virus has not been adequately measured. Female-to-female sex can include a variety of activities, and the risk relative to all activities is still not known. It is thought that oral sex alone poses a relatively low risk,⁽⁴⁾ and acts that may result in vaginal trauma, such as sharing sex toys without condoms or digital play with finger cuts or sharp nails, might pose higher risk.

To date, there have been no studies that have rigorously examined female-to-female sexual acts or cunnilingus as a risk for HIV transmission, but there are a number of reported cases of transmission.⁽⁵⁾ Only one study has looked at HIV-discordant lesbian couples (where one woman is infected and the other isn't). Although this study followed only 10 couples and only over a short period of time, they found no seroconversions.⁽⁶⁾

What are barriers to prevention?

Social, environmental and economic factors can be a barrier to prevention. WSW who are poor, drug addicted, lack adequate job training, are homeless or who fear violence may turn to prostitution or engage in sex with men for survival.(4) Attention to more immediate concerns of food, housing and addiction often takes priority over future concerns of HIV infection.

Expectations of heterosexuality and negative social or cultural attitudes towards homosexuality may serve to increase risk behaviors among some WSW. A study in San Francisco, CA, found that young lesbians engaged in high rates of alcohol and drug use, unprotected sex with men and sexual experimentation with young gay men as a way of coping with societal pressures.(7)

At-risk WSW are often invisible or not recognized within other groups such as crack-smokers and injection drug users, the homeless, commercial sex workers and prisoners. WSW who have sex with men may identify with different communities depending on the gender of their current sex partner. Prevention efforts should take this into account, and recognize that bisexual women may be most effectively reached through programs targeted to high risk heterosexual women.(7)

What's being done?

Prevention programs that focus specifically on WSW and HIV are still extremely limited, but the following projects have made a difference. The Lesbian AIDS Project (LAP) at GMHC in New York City, NY, provides multiple services to both HIV- and HIV+ WSW. LAP runs groups, safer sex workshops and a hotline. At-risk and HIV+ lesbians on staff provide education and outreach in the community including in women's prisons and recovery settings.(8)

In San Francisco, CA, Lyon-Martin Women's Health Services trained lesbians and bisexual women as peer educators to deliver safer sex information in women's bars, dance clubs and sex clubs. Affectionately known as the "Safer Sex Sluts," the peer educators are "dedicated to demolishing denial" by presenting skits, giving workshops and individual consultations and handing out condoms and lubricant.(9)

A community-based outreach project in Hollywood, CA, targeted street-based high-risk gay, bisexual, lesbian and transgender drug users. Based on a harm reduction model, the program provided support groups, peer counseling, referrals, prevention packages and hygiene kits.(10)

In Guatemala, a public space for lesbians, transvestites and gay/bisexual men opened to provide a safe environment for self-expression free of alcohol, sex and drugs. The Culture House sponsors creative workshops and classes in pottery, photography, literature, English and French, among others. They also sponsor conferences and round tables on issues such as violations of human rights, attitudes of the Catholic church towards gays and lesbians, staying HIV-negative and legal aspects of AIDS.(11)

What still needs to be done?

Definitive research on sexual practices, sexual risks, partnering choices and demographic characteristics of WSW are needed. Effective HIV prevention for WSW must take into account their sexual identity as well as their sexual behavior and drug use activity. Distinguishing WSW by their sexual identity may be crucial in targeting prevention messages.

Service providers and health care workers must be sensitized to the needs of WSW and be trained to conduct risk assessments that are not heterosexually biased. Many service providers assume that women who are HIV+ are exclusively heterosexual.(12) If a woman says that she

has had sex with a man, most will stop at that first question and don't proceed to ask if she has also had sex with a woman. Likewise, if a woman reports injection drug use, many will not proceed to sexual behavior questions, assuming drug use is the main risk. This not only affects the care and education a WSW may receive, but also leads to poor documentation on risk behavior forms and inadequate reporting of WSW HIV rates.

As a group, WSW have been invisible in the Centers for Disease Control and Prevention (CDC) HIV classification system. While categories of risk groups for men include men who have sex with men, injecting drug use and heterosexual contact, among others, there is no category for WSW. Efforts to more clearly identify WSW within the CDC's current surveillance system are underway.⁽¹³⁾ Information on the actual number of WSW among AIDS cases will bring to light the need for targeted prevention programs in this population.

The most effective prevention message for WSW is still unclear. Some groups contend that we need to focus on what's causing HIV risk for the majority of WSW -- drug use and sex with men -- rather than focus on issues of female-to-female transmission. Education and outreach should focus on cleaning or using new needles and using condoms and lubricant for anal and vaginal sex with men.⁽¹⁴⁾

It is unconscionable that after 15 years of the HIV epidemic, HIV+ women still don't have accurate information about risk in order to know what to do or not do sexually with their female partners. A comprehensive HIV prevention strategy uses a variety of elements to protect as many people at risk as possible. Accurate information on female-to-female sexual transmission and HIV incidence, as well as what factors influence risk taking among WSW, will be key to protecting women who have sex with women.

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January 1997. Fact Sheet #24E

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DEADLY OVERCAUTION: FDA'S DRUG APPROVAL PROCESS

by Sam Kazman

When the federal Food and Drug Administration announces its approval of an important new drug, the event is invariably portrayed as an administrative achievement. This has always puzzled me. It seems that a question hangs over these announcements that almost always goes unasked, though I understand why FDA might not care to answer it. The question is this: If a drug that has just been approved by FDA will start saving lives tomorrow, then how many people died yesterday waiting for the agency to act?

By "yesterday" I do not just mean the day before; I mean the two to three years that it generally takes FDA to approve a New Drug Application (NDA). Under federal law, no new drug can be marketed in this country until FDA approves it as safe and effective. FDA makes its finding on the basis of the manufacturer's NDA, which may contain over 100,000 pages of data from clinical tests that took from two to ten years to complete. During all this time the drug is unavailable to physicians and the public, except on a very limited basis as part of some clinical trial.

FDA, of course, is not the cause of all clinical testing; much of it is a necessary part of drug development and would occur even in the absence of FDA regulation. But it is clear that these regulations have made the development of new drugs significantly more expensive and time-consuming. Studies indicate that FDA's requirements have more than doubled development costs

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for approved drugs and have substantially reduced the rate at which new drugs are introduced, creating a large lag in the availability of new drugs in this country as measured against comparable foreign countries.¹

While FDA's defenders dispute the magnitude of these impacts, their essential argument is that these effects are far outweighed by the protection that FDA provides against unsafe and ineffective drugs. Their arguments inevitably go back to the event that led to the present day FDA and that is paradigmatic in any discussion of drug regulatory policy--thalidomide.

THALIDOMIDE AND THE EXPANSION OF FDA

Thalidomide was introduced in Germany in 1957 as a sedative distinguished by its nontoxicity. It was eventually sold in over 40 countries before its link to severe birth defects became apparent. In the United States approval for thalidomide, requested in 1960, was withheld by its FDA reviewer, Dr. Frances Kelsey, while she investigated reports that the drug caused peripheral nerve damage. In 1961 news of thalidomide's fetal effects led to the drug's withdrawal from the world market. Because of Dr. Kelsey's actions the drug was never sold in this country, and the US was largely spared the thousands of birth defects that occurred abroad. Dr. Kelsey received the President's Gold Medal for Distinguished Service for her work.

The thalidomide catastrophe was the catalyst for a major expansion of FDA's powers in 1962 under the Kefauver-Harris amendments to the Food, Drug and Cosmetic Act. The earlier statute, enacted in 1938, had prohibited the marketing of new drugs until they were found to be safe by FDA. The 1962 amendments added a new requirement--drugs would now have to be found to be both safe and effective before they could be introduced. This was ironic, because the threat posed by thalidomide was one of safety, not efficacy, and FDA's review powers under the 1938 act had succeeded in barring it from the American market.

The 1962 amendments also gave FDA far greater power over human testing of new drugs. Clinical trials of new drugs are generally performed in three stages: Phase

1 tests are aimed at obtaining basic data on drug toxicity and side effects, and are usually conducted on a small number of healthy subjects (usually under 100). Phase 2 tests study effectiveness as well as side effects, and generally involve several hundred subjects divided into treatment and control groups. Phase 3 testing examines more detailed issues such as optimal dosage and involves hundreds to thousands of subjects over multi-year periods.

Under the 1962 amendments all clinical (i.e., human) testing of new drugs, and of previously approved drugs being studied for new uses, must be cleared in advance by FDA under its investigational new drug (IND) procedures. FDA approval of an IND application to begin clinically testing a new drug hinges on such factors as the adequacy of pre-clinical (animal) testing, the details of the proposed test plan and the risk to which human participants will be subjected. Even after they are underway, approved tests can be halted if FDA subsequently becomes dissatisfied with them.

FDA's powers were expanded in other ways as well. Under the 1938 act NDAs were automatically approved unless the agency denied them. Under the new law it is disapproval that is automatic; for an NDA to be approved FDA now has to make an affirmative finding of safety and efficacy. Moreover, the claims that a manufacturer can make for a drug are limited to those approved by the agency for the drug's label.

The 1962 amendments fundamentally changed the nature of both the agency and the drug development process. "FDA shifted after 1962 from essentially an evaluator of evidence and research findings at the end of the R and D process to an active participant in the process itself,"² producing a transfer of "primary decision-making authority in pharmaceuticals from market mechanisms to a centralized regulatory authority."³

MORE GOVERNMENT, FEWER NEW DRUGS

While the 1962 amendments were aimed at protecting public health, it gradually became evident that they were seriously restricting pharmaceutical innovation in this country. Between 1962 and 1967 the average review time for an NDA more than tripled, rising from seven

months to thirty months.⁴ Despite numerous claims of FDA streamlining in recent years, average NDA review time has not improved, and ended the 1980's at over 32 months per application.⁵

The higher standards for NDA approval under the new law led to an increase in manufacturers' pre-NDA investigational work as well. The total development time for a new drug, which averaged from 4 to 6 years in the early 1960's, has now doubled to ten years.⁶ (See Chart 1, page 39.)

Development time is not the only factor that has worsened. The number of new drugs under development in the US declined as well. From 1975 to 1979 the number of new domestically developed drugs that entered human testing for the first time dropped to half the rate for the preceding decade. According to one study of this decline

the most common explanation given by the industry people was that severe scientific and political pressures were exerted in the mid-1970s on the industry's pre-clinical research. The increased FDA requirements were for more tests...and, perhaps more importantly, for large increases in the detail, standards, and documentation of the testing...One industry manager said that the simultaneous increase in...standards and attacks on particular drugs caused many industrial laboratories to virtually cease research on new drugs and to divert their resources into auditing their old data instead of working on new INDs...⁷

The most dramatic evidence of the effect of the 1962 amendments is the shift in drug innovation leadership between the US and Great Britain, which has scientific and medical standards comparable to ours. In the period immediately following the new law, before its full effects were felt, the US led Britain in new drug introduction. For the mutually available drugs (that is, drugs available in both countries) that were introduced between 1962 and 1965, the US had, on average, a six month lead in being the country of first introduction. However, from 1966 to 1971 Great Britain took the lead; on average, mutually available drugs were introduced 15 months earlier in Britain than in the US.⁸

Britain had a similar lead in exclusively available

CHART 1

Drug Development and Approval Process

Preclinical Testing

YEARS	1	2
Test Population	Laboratory and Animal Studies	
PURPOSE	Assess safety and biological activity	
% of all new drugs that pass		

F I L E I N D	Phase I	Phase II		Phase III		
	3	4	5	6	7	8
	20 to 80 Healthy Volunteers	100 to 300 Patient Volunteers		1,000 to 3,000 Patient Volunteers		
	Determine safety and dosage	Evaluate effectiveness. Look for side effects.		Verify effectiveness, monitor adverse reactions from long-term use.		
		Expedited Review: Phases II and III combined to shorten approval process on new medicines for serious & life-threatening diseases.				
	70 % of INDs	33 % of INDs		27 % of INDs		

F I L E I N D A	FDA		Approval
	9	10	
	Review usually takes about 2 to 3 years		Post-marketing safety monitoring
			Large-scale manufacturing
			Distribution
			Education
20 % of INDs			

It takes a decade on average for an experimental drug to travel from lab to medicine chest. Only five in 4,000 compounds screened in preclinical testing make it to human testing. One of these five tested in people is approved.

From: Pharmaceutical Manufacturers Association, *New Drug Approvals in 1989*.

drugs—that is, drugs introduced into only one of the two countries. Of the 98 drugs that became exclusively available between 1962 and 1971, 77 were introduced first in Britain.⁹

The most recent report on these trends shows that they have continued through the 1980s. From 1977 to 1987, 204 new drugs were introduced in the US; of these, 114 were available in Britain, with an average leadtime of more than five years per drug. On the other hand, of the 186 new drugs introduced into Britain during this period, only 41 were already available in the US and then only by an average of two and a half years. As for exclusively available drugs, there were 70 in Britain but only 54 in the US. The greatest lag times for the US were in the areas of cardiovascular, respiratory, central nervous system and cancer drugs.¹⁰

Just as alleged FDA reform has had no effect on NDA review time, it has similarly failed to reduce US drug lag. Average British leadtime in the second half of the period studied above, between 1983 and 1987, was as large as it was in the first half.

The study's authors concluded that, important drugs still become available later in the United States, some much later, than in the United Kingdom. This is true both for drugs representing important therapeutic gains, as well as for those representing modest or little gains. Moreover, the small difference in safety discontinuations in the two countries does not support the argument that delay protects the public from serious unforeseen adverse effects.¹¹

THE INVISIBLE RESULTS OF INEVITABLE BEHAVIOR

There are two basic types of errors which a drug regulator can make: the first is to mistakenly approve a drug which later turns out to have serious adverse side effects; the second type of error is to mistakenly reject, or even delay in approving, a beneficial drug. From a public health standpoint, both types of errors are equally serious in nature, because both will lead to the unnecessary loss of life. Overcaution in approving a needed drug can be just as deadly as lack of caution in approving a bad drug.¹²

The fundamental problem at FDA is that it is

overcautious in approving new drugs. This does not stem from its budget or from staff morale or from the individuals appointed to run it; it is a problem that is inherent in the agency's political nature, which makes it a creature of congressional oversight and media pressure. The thalidomide tragedy, the source of FDA's current powers, has become the guiding model for the agency. Every new drug is potentially another thalidomide. From the FDA commissioner to the bureau heads to the individual NDA reviewers, the message is clear: If you approve a drug with unanticipated side effects, both you and the agency will face the heat of newspaper headlines, television coverage and congressional hearings.

On the other hand, if FDA insists on more and more data from a manufacturer, and finally approves a drug which should have been on the market months or years before, there is no such price to pay. Drug lag's victims and their families will hardly be complaining, because they won't know what hit them. They do not know what INDs and NDAs lie waiting for approval at FDA, nor do they follow pharmaceutical news from abroad or progress reports on clinical trials. (Unless, that is, they are sufficiently lucky, rich or politically connected to get into such a trial.) They only know that there is nothing their doctors can do for them. From the standpoint of media and politics, they are invisible.

As former FDA Commissioner Alexander Schmidt once stated,

In all of FDA's history, I am unable to find a single instance where a Congressional committee investigated the failure of FDA to approve a new drug. But, the times when hearings have been held to criticize our approval of new drugs have been so frequent that we aren't able to count them... The message to FDA staff could not be clearer. Whenever a controversy over a new drug is resolved by its approval, the Agency and the individuals involved likely will be investigated. Whenever such a drug is disapproved, no inquiry will be made. The Congressional pressure for our negative action on new drug applications is, therefore, intense. And it seems to be increasing...¹⁸

The clinical research director of a major pharmaceutical

company involved in Alzheimer's research put it more directly:

There won't be any breakthrough products out there because every time the trials run into seizure or liver enzymes, the risk will be emphasized and the benefit will be ignored.¹⁴

Similar sentiments were expressed by officials of the National Cancer Institute, who accused FDA of being "mired in a 1960s philosophy of drug development, viewing all new agents as...poisons."¹⁵

The political invisibility of drug lag's victims is the major reason for FDA's inherent overcaution in approving new drugs. Caution may sound like a good thing when it comes to public health, but there are times when overcaution can be deadlier than lack of caution, which is why we do not elaborately stress-test a rope before throwing it to a drowning man.

A stark example of FDA's skewed treatment of risks and benefits is the agency's ten year delay (from 1967 to 1976) in approving a variety of beta blockers to reduce heart attacks. FDA Commissioner Donald Kennedy defended this delay as follows:

A major reason...was the suspicion that a number of B-blockers might be tumorigenic, and the resulting (FDA) requirement that long-term animal studies be undertaken to investigate this possibility...It (now) appears that certain B-blockers are potential tumorigens...Since B-blockers (are) intended for long-term use in a great many patients, the FDA's...decision to require long-term carcinogenic-effect testing before clinical use spared patients in the US a potentially dangerous kind of exposure.¹⁶

But to Dr. William M. Wardell, a major scholar of drug regulation, this is a very minor side of the story:

The proper use of (the B-blocker) practolol...could now be saving 10,000 lives each year in the US at a cost, in terms of side effects, that can now be made trivial by comparison...These important advances are what Dr. Kennedy triumphantly takes credit for 'protecting' us from; the concept of risk avoidance has been turned pyrrhically on its head.

In addition to 'saving' the US from the only drugs that

had, up to 1977, been definitely shown to reduce postinfarction mortality, the FDA's B-blocker policy has set back cardiovascular therapy in this country by years. At a time when the frontiers of B-blocker research throughout the world had moved on to the question of preventing coronary death and reinfarction, economic, clinical, and intellectual resources of both the FDA and industry in the US went into reexamining... efficacy and toxicity...(about which the answers were already well known...); this scientific wheel-spinning lasted for approximately seven years...¹⁷

FDA's action may make little medical sense, but unfortunately it makes perfect political sense. In terms of congressional reaction and media coverage, the post-approval discovery that certain beta blockers induced tumors would have been devastating to FDA. Even a score of unanticipated deaths from a new drug are enough to set Congress off,¹⁸ while the loss of several thousand lives due to a delayed approval has practically no political impact.

FDA's skewed incentives have other results as well. When the agency believes that satisfactory treatment for a certain illness is already available, new drugs for it will frequently have to pass an even higher standard of proof. Treatments thus tend to become frozen at levels that are only moderately successful—after all, why take a chance on something new when the old is adequate? (And if the new drug has some unrealized potential, who'll complain about its absence?)

The possibility of unapproved use can also become a back-door factor in the denial of an NDA. Levamisole, for example, has recently shown such great promise in treating colon cancer that FDA is permitting its distribution while clinical tests are still underway. The original levamisole NDA, however, filed in the early 1970's for its use as an anti-worm drug, was never approved by FDA. The official reason was that adequate anti-worm agents were already available. The real reason appeared to be concern that levamisole would be put to unauthorized use against cancer, since reports of the drug's immunity-boosting effects were already circulating at that time.¹⁹ Thus, yet another revolutionary drug turns

out to be a breakthrough in bureaucracy rather than in medicine.

RU-486, the new French abortion pill, may meet a similar fate. Its consideration by FDA will undoubtedly be mired in the abortion debate. The drug, however, has also shown promise against brain and spinal tumors—uses which will be submerged by political opposition to its availability.

The FDA process has also created a regulatory structure which benefits certain segments of the pharmaceutical industry. Large, established firms have developed an expertise in dealing with FDA that probably accounts for a good part of their capital value; they are also able to spread the costs of FDA compliance over a large product line. For new entrants in the field, on the other hand, FDA regulation is a sizable competitive barrier.²⁰

AIDS AND THE ILLUSION OF FDA REFORM

The major exception to drug lag's invisibility has been the AIDS crisis and the emergence of a nationwide network of AIDS activist organizations. More than any other public health issue, AIDS has highlighted the grotesque consequences of FDA policy. It has presented the spectacle of federal officials denying unapproved drugs to incurably ill people on the ground that the denial is for their own good, while AIDS victims and their supporters resort to drug smuggling in order to preserve their dignity and autonomy. The October 1988 AIDS demonstration at FDA headquarters marked the first time that the agency has been physically confronted, en masse, by its victims.

The AIDS crisis has sparked a number of minor reforms. Access to experimental drugs has been made slightly easier through such new procedures as "treatment INDs" and "parallel tracking," under which promising drugs can be used for treatment before they receive final FDA approval. FDA is allowing the limited importation of unapproved foreign drugs by individuals (though at the same time, paradoxically, these same drugs still cannot be legally obtained from domestic manufacturers). The agency has begun to accept test data on experimental drugs from community-based programs, a significant

departure from the centralized clinical trials that were previously an absolute prerequisite for FDA approval.

These changes sound impressive, but they are only the latest in a long series of agency reforms that have failed to significantly improve drug regulation. In 1975, for example, the agency began a "priority review" to speed the approval of promising new drugs. This fast-tracking has had some apparent successes—AZT, for example, the only drug yet approved for treating AIDS, went through the NDA process in a recordbreaking 107 days. Nonetheless, fast-tracking depends on FDA's alleged ability to pick winners in advance—a claim that is as ubiquitous among government planners as it is unsupported. Consider this account of FDA's 1978 approval of valproate sodium for treating epilepsy:

Although this drug was acted on with alacrity in the glare of unprecedented publicity in the final stages leading to its NDA approval...its early history is not one of speed...The IND study on this drug was submitted in December 1974, by which time the drug had been marketed abroad for several years and was already recognized as a drug of choice for certain types of epilepsy. Nevertheless, the FDA's classification system assigned it to class B (i.e., not meriting the fast-track treatment). It was not until October 1977 that the drug was first referred to the FDA's Neurologic Drug Advisory Committee. The fact that the FDA's system failed to recognize the importance of an already-marketed drug of choice does not make one sanguine about the FDA's claimed ability to identify important new drugs even earlier, i.e., at the investigational stage—before a drug's therapeutic potential can be predicted by anyone—when the research process is most susceptible to inhibitory regulation.²¹

Just as the AIDS crisis has not produced any fundamental reform of FDA, it has also not improved the media's understanding of the agency's role in drug development. Most FDA actions are not agency accomplishments; they are the termination of FDA restraints on *private* accomplishments. Despite countless stories on AIDS protests, drug smuggling and underground testing, however, reporters continue to get this simple fact

wrong. In early 1990, for example, FDA allowed AZT's manufacturer to halve the drug's recommended dosage, a very significant step given AZT's high cost and toxicity. The dosage cut, however, was almost universally reported as an FDA achievement, despite the fact that all the agency had done was to approve a request made by the manufacturer several months earlier.²²

The recent FDA reforms, moreover, are jeopardized by new moves to tighten the drug approval process. The generic drug scandal, in which certain firms were found to have bribed FDA staffers to delay their competitors' NDAs, has created a legislative backlash to the little deregulation that FDA has accomplished. Similarly, the General Accounting Office recently reported that more than half of the drugs introduced in 1976 to 1985 had side effects that were discovered only after they had been approved.²³ In its demand for pre-approval omniscience, of course, GAO totally ignores the extent to which a more elaborate NDA review process would further delay new drug approval—an inexplicable approach, especially since GAO itself has criticized FDA's slowness.²⁴ GAO's new report, requested by a leading congressional advocate of stricter FDA regulation, has become another supposedly weighty argument against FDA reform.

The AIDS crisis became an exception to drug lag's invisibility because of gay political power. Had those at risk for AIDS been less organized, as is the case with victims of most critical diseases, the availability of AIDS treatments would be a fraction of its current level. This may be the way politics works, but it is not the way medicine should work.

PUTTING SOME NUMBERS ON THE FACELESS

FDA claims to assure drug safety and efficacy. Just what these qualities are, and whether government is in fact necessary for their assurance, are debatable questions. But regardless of how we ultimately answer them, we should have some handle on what FDA's drug approval regime costs us. After all, when a salesman tells you that his product is absolutely essential, it usually is not a bad idea to ask the price.

FDA's \$100 million drug review budget is the most

obvious component of this price, but it is also the most minor. The major cost is the invisible one—the therapeutic benefits of new drugs that we lose while these drugs are under review. For example:

Misoprostol and Gastric Ulcer Bleeding

In December 1988, FDA announced its approval of misoprostol—the first drug to prevent the gastric ulcers that are caused by aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs). These medications are frequently taken in large doses by arthritis sufferers, and the gastric ulcers which frequently result undetected from their use cause 10,000 to 20,000 deaths each year through internal bleeding and other complications. Misoprostol is reported to produce a 15-fold reduction in these gastric ulcers, and its life-saving potential led FDA to give its highest therapeutic potential rating, 1A, to the drug's NDA.²⁵

The NDA was approved by the agency in a relatively rapid nine and a half months. Nonetheless, by the time the drug was approved in the US it was already available in 43 foreign countries, in some of them since 1985.

In a press release accompanying the misoprostol approval, FDA Commissioner Frank Young stated, "This drug should save lives as well as costly hospitalizations." Thus, the question with which this article began—if a new drug will save lives after its approval, then how many lives were lost while it was being reviewed?

This is but one aspect of the drug lag that has been discussed above. It does not measure FDA's burden on pre-NDA development time. On the other hand, it avoids the complexity of international comparisons by focusing on a distinct time period during which a drug's unavailability is clearly FDA's doing—the period that begins with the filing of an NDA and ends with its approval.

Moreover, this approach is similar to that taken by many federal agencies in publicizing the hazards of toxic substances and other health perils. Why not treat the hazards of FDA regulation in the same way?

The calculation for misoprostol would be as follows. If the drug is, as reported, 94 percent effective and if, as

FDA estimates, there are 10,000 to 20,000 gastric ulcer deaths annually due to NSAID use, then misoprostol potentially could have saved 8,000 to 15,000 lives during FDA's nine and a half month review period.

This post-approval audit is admittedly inexact. Misoprostol may never reach all of those who might benefit from it, and it certainly did not achieve such widespread use in its first months on the market. On the other hand, misoprostol's marketing was on hold for the full duration of FDA's review period; whatever level of use misoprostol reaches a year from now, we can assume that same level would have been reached nine and a half months earlier were it not for this FDA review.

In short, 8,000 to 15,000 lives is a fair starting point for calculating the cost of FDA's review of misoprostol. FDA can come up with its own figures if it disputes this, but at least let it come up with *something*. Had Frank Young announced that "misoprostol will save lives, but we did lose several thousand people while FDA went over the manufacturer's paperwork," the public's perception of the agency might have undergone a rather fundamental shift.

As usual, however, the drug lag angle did not appear in coverage of the misoprostol story. Its approval was reported as a triumph of rapid administrative action. Its manufacturer, pleased with FDA's speed, was not about to antagonize the agency that controlled its livelihood. Those who might have been saved had the drug been available earlier rested in peace.

Thrombolytic Therapy for Heart Attacks

Drug lag was a more prominent issue in FDA's 1987 approval of thrombolytic (clot-dissolving) therapy for heart attacks, but it was still ultimately skirted by the agency.

In November 1987, FDA approved streptokinase as the first drug which could be intravenously administered to reopen the blocked coronary arteries of heart attack victims. Streptokinase had been shown to reduce in-hospital mortality among heart attack patients by 18 percent. In the US approximately 700,000 heart attack patients are hospitalized annually, of whom 9 percent die in-hospital. Thus, streptokinase could potentially save 11,000 of these lives each year.

FDA's approval of this use for streptokinase came a full two years after its NDA was filed, which means that 22,000 deaths might have been prevented in the interim.²⁶ Even after an FDA advisory committee recommended approval of the NDA in May 1987, it still took the agency six months to issue its decision.

The streptokinase approval was overshadowed by the agency's handling of TPA, a genetically engineered thrombolytic agent that appeared to be even better than streptokinase. In 1985 the National Heart, Lung and Blood Institute (NHLBI) had abruptly halted a study comparing the two drugs because TPA appeared to be so much more effective that its researchers decided they could not ethically withhold TPA from any of their test subjects. TPA's manufacturer, Genentech, filed its NDA in April 1986.

At its May 1987 meeting however, in a decision that stunned many observers, the same FDA advisory committee that recommended approval of streptokinase voted against the TPA application. The committee was satisfied that TPA was effective in dissolving clots, but it wanted mortality data as well—that is, statistics showing that TPA-treated patients survived longer than untreated patients. Among the committee's concerns was the incidence of strokes that had occurred among some TPA patients.

In short, while the NHLBI researchers viewed TPA's unavailability to some of their trial subjects as so medically unethical as to require premature termination of their study, the FDA advisory committee recommended that the drug be withheld from the entire nation.

The advisory committee's recommendation was heavily criticized in certain quarters. The *Wall Street Journal* ran a series of articles and editorials which indicated that much of the dispute over TPA stemmed from a jurisdictional battle between two FDA bureaus, one responsible for drugs, the other for genetically engineered products. *Science*, one of the world's most respected scientific journals, editorialized that,

when a regulatory agency that licenses drugs for heart attacks stumbles, it may have not only egg on its face but blood on its hands...A drug that dissolves blood clots should no longer have to

answer whether such an action prolongs life.²⁷

FDA did finally approve TPA shortly after it acted on the streptokinase NDA. By that time TPA was available in eight other countries, among them France, Austria, New Zealand and Germany. At his press conference announcing the approval, Commissioner Young brushed aside criticism of FDA's delay on TPA as the work of stock speculators, stating that "to be able to clean out an artery but at the same time produce a massive stroke would not be a very good result."

To eat chicken but at the same time choke to death on a bone would not be a very good result either. It is also a strawman proposition. A bad outcome is meaningless unless we can weigh the likelihood of its occurrence against the anticipated benefit of the action.

Commissioner Young went on to instruct the public on the need for speed in treating a suspected heart attack. "Don't deny the symptoms. Don't wait," he urged. "Seek the care of a physician so that you can make yourself available for this type of therapy." This recommendation was a far cry from FDA's own approach in approving the drug.²⁸

The post-approval audit described above could be applied to any newly approved drug. By putting numbers on an otherwise invisible cost of FDA review, such an audit would bring some balance to public perception of FDA's function.

Is such an audit feasible? Commissioner Young didn't doubt it when I asked him about this in 1989: "Yes, I think the balances can be done. Have they been focused on in that way? Absolutely not."

Would FDA do such an audit? This got a different response from the Commissioner:

We think that, in part, this is something that should be studied by others. We do have a job of getting drugs that are safe and effective on the market at a time when we can hardly meet our time limits as it is, though this scholarship is very important.²⁹

In short, don't hold your breath waiting for the agency to come out with these numbers.

On the other hand, FDA is not the only organization that could conduct a post-approval audit.

Within the federal government such agencies as the Council of Economic Advisers and the Office of Management and Budget would be well equipped to undertake such an audit, either periodically—examining all new drugs approved within a given time period—or on the occasion of major FDA drug approvals. Outside groups such as the National Academy of Sciences could perform the audit as well. What is important is that the numbers come out, so that FDA's announcements are received by something more than the uncritical applause that usually greets them.

ACCESS TO DRUGS—WITH FDA'S ADVICE, BUT WITHOUT ITS CONSENT

A post-approval audit would put needed pressure on FDA, but more is needed if we are to avoid the toll of the current system. Attempts at fine-tuning the regulatory process, such as treatment INDs, may produce small temporary improvements, but they inevitably run into the brick wall of a system committed to playing it safe no matter how deadly the consequences. Moreover, FDA's safety and efficacy criteria are valued by too large a segment of the public to make their abolition politically feasible.

There is, however, a simple way to preserve FDA's criteria while eliminating the deadly costs of the current regime: change FDA's veto power over new drugs to a system of certification. Let the agency continue to review safety and efficacy, but allow unapproved drugs, clearly labelled as such, to be available by prescription.

Under this approach those patients and physicians who wish to be guided by FDA's judgments would face no obstacle whatsoever; they could simply restrict themselves, as they do now, to approved drugs. But a critically ill individual, faced with the need to go beyond this circle of official approval, could do so under the care of a physician.

This approach would bring pharmacology in line with the rest of medical care, where government approval is the exception, not the rule. FDA, after all, does not approve surgical methods, yet we do not worry about podiatrists doing in-office brain transplants. Physicians

prescribing unapproved drugs would need good reasons under malpractice law for doing so, especially if approved alternatives were available. Patients using such drugs would know they were taking a special risk; unapproved drugs would bear the regulatory equivalent of a skull-and-crossbones and would be accompanied by informed consent documentation. And if FDA approval is truly medically valuable, then the use of these drugs would be remain relatively small.

Would snake oil be sold? Would patients be conned? Would unscrupulous doctors connive with fly-by-night drug makers to sell us elixirs that were worthless or worse? Perhaps, but these inequities already occur, and there is no reason to suppose that their costs outway the advantages of such an approach. In fact their incidence might well decline as unapproved drugs moved from the medical underworld into legitimacy, just as alcohol poisonings dropped when Prohibition was repealed.³⁰ It is the current centralized decisionmaking process, with its inherent bias, that holds the potential for true catastrophe.

Drug safety is not a hard and fast concept. At the scientific level, it is often the subject of intense disputes among experts. At the level of personal values and decisions, therapeutic risks that are acceptable to one person may be out of the question for another. At neither level should this be the subject of administrative edict. Drug safety "can be meaningfully defined only in terms of individual choice, not society-wide judgments of 'safety and efficacy.'"³¹ Government may attempt to educate us, but it has no business issuing across-the-board mandates on how we should protect our health and our lives.

We have all seen pictures of thalidomide babies, but we know nothing about the victims of FDA's 10-year delay in approving beta blockers, or of its 2-year delay on cardiac thrombolytics, or of any of the other lags that it has silently caused. This imbalance in knowledge is the driving force behind FDA's current drug approval system. That system is consistent with neither good government nor good science nor respect for individual liberty and dignity, and it is time we moved beyond it.

ENDNOTES

¹The following are among the key literature on drug lag: S. Peltzman, *Regulation of Pharmaceutical Innovation* (1974); W. M. Wardell & L. Lasagna, *Regulation and Drug Development* (1975); H. G. Grabowski & J. M. Vernon, *The Regulation of Pharmaceuticals* (1983).

²Grabowski & Vernon, *supra* at 4 (1983).

³*Id.*

⁴S. Peltzman, *supra* n. 1, at 18 (1974).

⁵Pharmaceutical Manufacturers Association, *New Drug Approvals in 1989* at 1.

⁶Grabowski & Vernon, *supra* n. 1, at 30-33.

⁷Wardell, May & Trimble, "New Drug Development By United States Pharmaceutical Firms," 32 *Clin. Pharm. & Therapeutics* 407, 415 (1982). The decline was found in "self-originated" new drugs—that is, compounds being tested by the US firms that had developed them. The rate of testing subsequently increased in the 1980s.

⁸Peltzman, *supra* n. 1, at 18.

⁹Wardell & Lasagna, *supra* n. 1, at 58-59.

¹⁰Kaltin, Mattison, Northington & Lasagna, "The Drug Lag: An Update of New Drug Introductions in the United States and in the United Kingdom, 1977 Through 1987," 46 *Clin. Pharm. & Therapeutics* 121 (1989).

¹¹*Id.* at 135.

¹²These are generally referred to as Type I and Type II errors. See, e.g., Grabowski & Vernon, *supra* n. 1, at 9-13.

¹³As quoted in Grabowski & Vernon, *supra* n. 1, at 5.

¹⁴Dr. Michael Murphy of Hoechst-Roussel, as quoted in "Wichita Falls Calls the FDA," *Wall Street Journal*, April 29, 1988, at 22.

¹⁵"Cancer Institute: AIDS drugs unduly delayed," *Chicago Tribune*, January 5, 1989, at 4.

¹⁶Kennedy, "A Calm Look at 'Drug Lag'," 239 *JAMA* 423, 425 (1978).

¹⁷Wardell, "A Close Inspection of the 'Calm Look,'" 239 *JAMA* 2004, 2010 (1978).

¹⁸See, e.g., "Drug Approval Hit—Congressional Panel Issues Scathing Report On Licensing of Drug Implicated in 30 Deaths," *Washington Post-Health*, July 21, 1987, at 6.

¹⁹H. Schwartz, "A 'Miracle' Drug That Languished Among the Worms," *Wall Street Journal*, July 18, 1989, at A22.

²⁰See e.g., "Plan to Speed Approval of Test Drugs Pits Small Companies Against Big Ones," *Wall Street Journal*, April 3, 1987, at 33.

²¹Wardell, *supra* n. 17.

²²Some typical headlines were "U.S. Halves Dosage For AIDS Drug" (*New York Times*) and "AZT Anti-AIDS Medication Cut in Half By FDA" (*Washington Times*). The opening line in another newspaper's story began "FDA today halved the recommend dose...." (*Washington Post*). The *Wall Street Journal's* article was a notable exception, headlined "FDA Lets Wellcome Cut Dosage..." (The stories all appeared in the January 17, 1990, issues of the above newspapers.)

²³GAO, *FDA Drug Review—Post Approval Risks, 1976-85*, April 1990 (GAO/PEMD-90-15).

²⁴See GAO, *FDA Drug Approval—A Lengthy Process That Delays The Availability of Important New Drugs*, May 1980 (HRD-80-64).

²⁵G. D. Searle & Co., Press Release, December 27, 1988.

²⁶Thrombolytic therapy might eventually go beyond hospital use, and be administered by paramedics and others in victims' homes and workplaces. *Circulation* 474 (1987). It would thus begin to reach the 400,000 heart attack victims who die annually before reaching a hospital. To the extent that FDA's delayed approval impeded this extension of thrombolysis, its effect in terms of lives lost is even greater.

The drug lag computation for streptokinase is slightly complicated by the fact that,

to a very limited extent, the drug was available for thrombolytic heart attack therapy prior to 1987. In 1982 FDA approved the drug for direct injection into coronary arteries, a procedure that is for more difficult than intravenous administration and that was used very infrequently.

²⁷"TPA and PDQ," 237 *Science* 341 (July 24, 1987).

²⁸A recent study casts some doubt on whether TPA is more effective than streptokinase, especially when these agents are used in conjunction with heparin. See, e.g., "Old Heart Drug Works as Well as Costly TPA in Study," *Wall Street Journal*, March 9, 1990, at B1. The current lack of any medical consensus on this issue illustrates the folly of leaving its resolution to a federal agency.

²⁹Administrative Conference of the US, Colloquy on the FDA Drug Approval Process in the AIDS Era (July 25, 1989), Transcript at 68, 71.

³⁰See, e.g., A. Sinclair, *Era of Excess: Social History of the Prohibition Movement* 201 (1964).

³¹D. Gieringer, "Compassion vs. Control: FDA Investigational Drug Regulation 24," *Cato Policy Analysis* (May 20, 1986). The author proposes the sale of unproven drugs using a scale of safety and efficacy ratings.

NEW YORK STATE DEPARTMENT OF HEALTH HIV UNINSURED CARE PROGRAMS ADAP - ADAP PLUS - HIV HOME CARE

PURPOSE: The New York State Department of Health AIDS Institute has established three programs for HIV Uninsured Care (ADAP, ADAP Plus and the HIV Home Care Program). The mission of these programs is to provide access to medical services and medications for all New York State residents with HIV/AIDS. The programs dual goals are: to empower the individual to seek, access and receive medical care and prescription drugs without cost; and to supply a stable and timely funding stream to health care providers, enabling them to use the revenues to develop program capacity to meet the needs of the uninsured HIV population.

BACKGROUND: The AIDS Drug Assistance Program (ADAP) began in 1987 as part of a national program to provide free HIV/AIDS drugs to low-income individuals not covered by Medicaid or adequate third-party insurance. ADAP has grown tremendously in both enrollment and drug coverage. In November 1991, the HIV Home Care Program, modeled on ADAP, was implemented through a federal (HRSA) demonstration grant. ADAP Plus was designed in a unique partnership between New York City and New York State, and through cooperative funding was implemented statewide in October 1992. All three programs are integrated and centrally administered, use a unified application form and coordinate outreach activities.

POPULATION SERVED: The programs serve HIV-infected New York State residents who are uninsured or under-insured and meet established residency, financial and medical criteria. The programs serve all populations affected by AIDS in New York State, with participant demographics changing over the years to reflect changes in the epidemic. As of 4/1/98 participant enrollment was: ADAP = 43,824 cumulative with 12,814 active clients; ADAP Plus = 33,117 cumulative with 12,006 active; and Home Care = 3,599 cumulative with an active caseload of 71.

ELIGIBILITY CRITERIA: Participants must meet the following criteria:

(1) Residency - New York State (U.S. citizenship is not required.)

(2) Medical -

ADAP and ADAP Plus

- HIV-infection (asymptomatics are eligible.)

Home Care

- AIDS or HIV illness and chronic medical dependency due to physical or cognitive impairment from HIV infection.

(3) Financial

- Income less than \$44,000/year for a household of one, \$59,200 for two, and \$74,400 for three or more, and
- Liquid Assets less than \$25,000

ENROLLMENT PROCESS - Applicants apply to the program, providing proof of residency, income and assets. A Medical Application from a physician is required, verifying HIV-infection and indicating the applicant's medical status. A treatment plan by a physician must also be submitted for Home Care applicants. A single application form can be used to enroll in ADAP, ADAP Plus and the Home Care Uninsured Program. Enrollment in the programs is coordinated for all eligible individuals. Upon determination of eligibility, a Medical Card is issued which may be used to receive care from an enrolled provider.

SERVICES: The Programs' service benefit package has been restructured several times in 1996 based on available funding limitations. As of 1/1/98, the ADAP Formulary consists of over 200 drugs, including: antiretroviral therapies; antineoplastics; prophylaxis and treatments for opportunistic infections; and medications for related conditions. ADAP Plus covers a full range of HIV Primary Care services, provided on an outpatient ambulatory basis including: annual comprehensive medical evaluation; clinical HIV disease monitoring; drug and immunotherapy administration; the treatment of both HIV related and non-HIV related illness; ambulatory surgery; nutrition and laboratory services. Services covered through the HIV Home Care Uninsured Program include: skilled nursing; personal care; homemaker and home health aid services; intravenous administration and supplies; and durable medical equipment. New drugs and services are added based on available funding, the changing clinical profile of the epidemic and the most recent clinical trials data.

PROVIDERS: ADAP has enrolled over 2,800 local pharmacies. ADAP Plus has enrolled 148 hospitals and clinics (303 service sites), 446 private physicians and 115 clinical laboratories. The HIV Home Care Program has enrolled 729 Home Health Agencies, Long Term Home Health Care Programs, Hospices and Licensed Home Care Service Agencies.

FUNDING: The programs are funded through a partnership between New York State and the HIV Planning Councils of the New York City, Long Island, the Lower Hudson, and Dutchess County Regions, using funds from Titles I and II of the federal Ryan White CARE Act. The Department of Health also uses funds from the New York State Health Care Reform Act of 1996 for services and state funds to pay for a portion of the administration of the programs.

ADVISORY COUNCIL: An Advisory Council has been established to provide input, guidance and recommendations to the programs from a wide variety of perspectives. The Council consists of a Steering Committee and a Clinical Subcommittee. The Steering Committee provides overall program and policy guidance and recommendations to the AIDS Institute. It is comprised of representatives of Title I Planning Councils, local and state government, health care providers, agencies and associations, the infected/affected population, as well as representatives from the Clinical Subcommittee. The Clinical Subcommittee advises and makes recommendations on clinical aspects of the programs, and includes persons living with AIDS/HIV, and clinicians with expertise in various specialties who are actively treating individuals with HIV/AIDS.

MEDICAID - Individuals enrolled in Medicaid are not eligible for the programs. Individuals awaiting Medicaid eligibility determination or having Medicaid Spenddown requirements are eligible. The programs can assist individuals to meet their Medicaid Spenddown requirements. The program interfaces with Medicaid to prevent duplication of enrollment and billing. The programs seek to identify individuals who are potentially eligible for Medicaid and encourage them to apply to Medicaid. Medicaid is the preferred medical coverage for individuals who meet their eligibility requirements, because of Medicaid's broader range of covered services.

ADDITIONAL INFORMATION/APPLICATIONS:

Call tollfree: 1-800-542-2437 (in NYS)
or call 518-459-1641 (Out of State)

or write: EMPIRE STATION, P.O. BOX 2052, ALBANY, N.Y. 12220-2052

April 1, 1998

**NEW YORK STATE DEPARTMENT OF HEALTH
AIDS DRUG ASSISTANCE PROGRAM (ADAP)
FORMULARY - DECEMBER 17, 1997**

ANTIRETROVIRAL THERAPY *

Nucleoside Analogs
didanosine (ddI, Videx)
lamivudine (3TC, Epivir)
stavudine (d4T, Zerit)
zalcitabine (ddC, HIViD)
zidovudine (AZT, Retrovir)
lamivudine/zidovudine (Combivir)

Protease Inhibitors
indinavir (Crivivan)
nelfinavir (Viracept)
ritonavir (Norvir)
saquinavir (Invirase, Fortovase)

**Non-Nucleoside Reverse
Transcriptase Inhibitors**
nevirapine (Viramune)
delavirdine (Rescriptor)

PCP PROPHYLAXIS & TREATMENT

atovaquone
clindamycin
dapsone
leucovorin
pentamidine
primaquine
sulfadoxine/pyrimethamine
trimethoprim
trimethoprim/sulfamethoxazole

ANTINEOPLASTICS

alpha interferon
bleomycin
cyclophosphamide
cytarabine
dexamethasone
doxorubicin
etoposide
liposomal doxorubicin
liposomal daunorubicin
lomustine
methotrexate
paclitaxel
prednisone
procarbazine
vinblastine
vincristine

OPPORTUNISTIC INFECTIONS

Herpes Infections
acyclovir
famciclovir
penciclovir

CMV disease
foscarnet
ganciclovir
cidofovir
probencid

Fungal infections
amphotericin B
clotrimazole
fluconazole
flucytosine
griseofulvin
itraconazole
ketoconazole
miconazole
nystatin
terconazole

Cryptosporidiosis
paromomycin

Microsporidiosis
albendazole

Mycobacterial Infections

amikacin
azithromycin
ceapreomycin
ciprofloxacin
clarithromycin
cycloserine
ethambutol
ethionamide
isoniazid
kanamycin
ofloxacin
para-amino salicylic acid
pyrazinamide
rifabutin
rifampin
rifampin in combination
streptomycin

Toxoplasmosis

azithromycin
clindamycin
leucovorin
pyrimethamine
sulfadiazine
sulfamethoxazole
triple sulfa

OTHER HIV/AIDS RELATED CONDITIONS

Wasting Syndrome
cyproheptadine HCl
dronabinol
megestrol acetate

Prevention of bacterial infections in children ONLY.
intravenous immune globulin

Condyloma acuminata.
podofilox
imiquimod

Prevention of dental cavities.
fluoride

Hepatitis
hepatitis A & B vaccines

DRUGS REQUIRING PRIOR AUTHORIZATION

Request Form and Guidelines available (1-800-542-2437)

epoetin alfa (Procrit - ONLY)

for AIDS related anemia, with: Hct < 30% and/or Hgb < 10g/dl;
and serum erythropoietin levels < 500mU/ml.

filgrastim

for severe neutropenia due to: chemotherapy; or drug toxicity or HIV
disease with ANC < 500/mm³.

NOTES: Formulary is subject to change based on available funds.

* Some anti-retroviral combinations may be subject to utilization review thresholds.

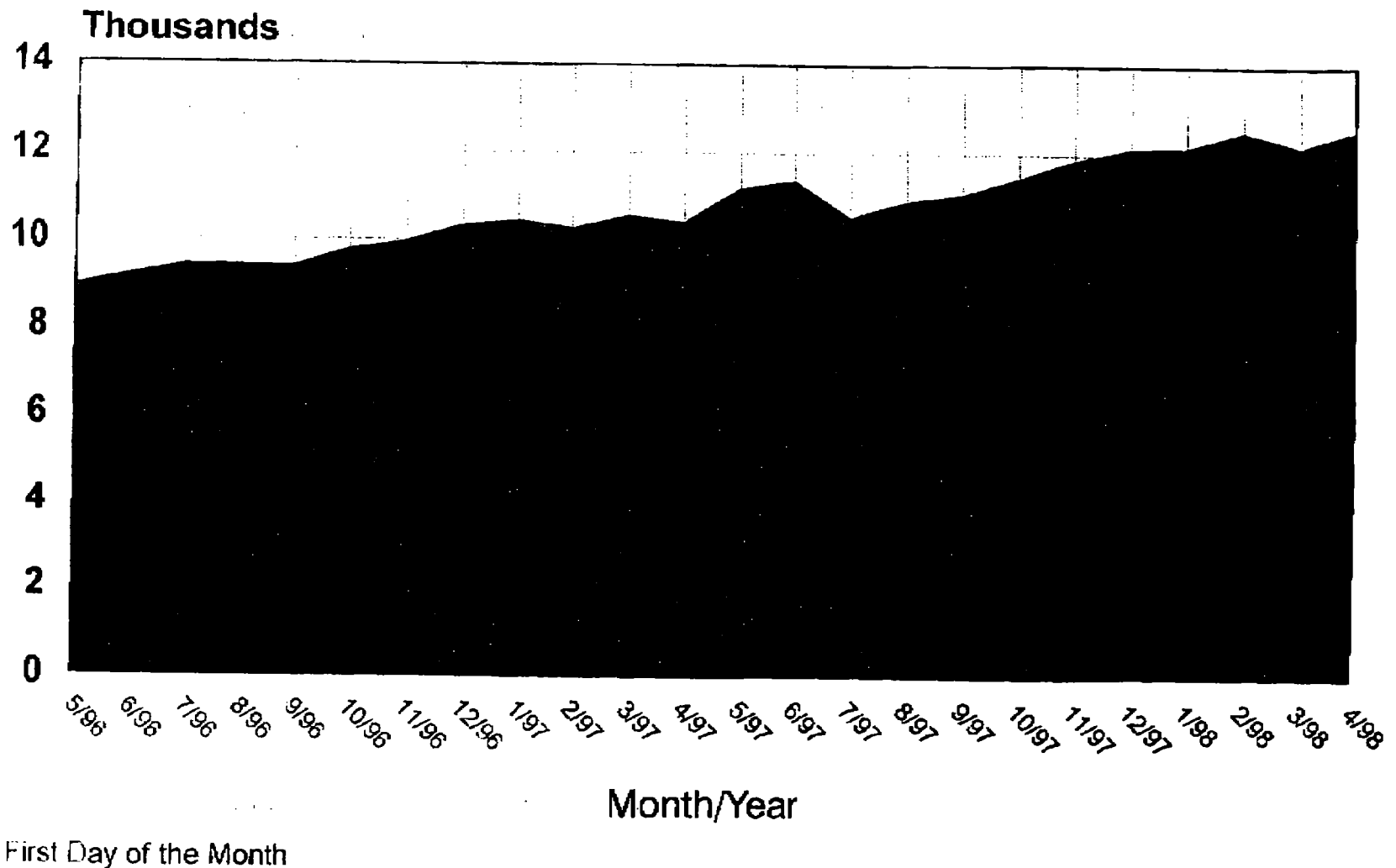
**NEW YORK STATE DEPARTMENT OF HEALTH
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ANTIBIOTICS amoxicillin amoxicillin K + clavulanate ampicillin aztreonam bacitracin cefaclor cefadroxil cefazolin cefixime cefoxitin cefpodoxime cefprozil ceftazidime ceftioxone cefuroxime cephalexin cephradine chloramphenicol cloxacillin dicloxacillin doxycycline erythromycin erythromycin ethylsuccinate erythromycin ethylsuccinate and sulfisoxazole acetyl furazolidone gentamicin imipenem - cilastatin levofloxacin loracarbef metronidazole minocycline nitrofurantoin penicillin G penicillin V potassium sparfloxacin spectinomycin tetracycline ticarcillin K + clavulanate tobramycin vancomycin	ANALGESICS butorbital combination w/w/o/ codeine codeine w/w/o/ ASA, APAP diclofenac diflunisal fenoprofen fentanyl (patch only) flurbiprofen hydrocodone w/ ASA, APAP hydromorphone ibuprofen indomethacin ketoprofen ketorolac tromethamine levorphanol tartrate methadone hydrochloride @ morphine sulfate naproxen oxycodone w/w/o/ ASA, APAP piroxicam sulindac tolmetin	PSYCHOTROPICS - CONT. diazepam doxepin hydrochloride fluoxetine fluphenazine flurazepam fluvoxamine halazepam haloperidol imipramine lithium carbonate lithium citrate lorazepam loxapine mesoridazine methylphenidate molindone nefazodone nortriptyline olanzapine oxazepam paroxetine pemoline pentobarbital perphenazine prazepam prochlorperazine risperidone secobarbital sertraline temazepam thioridazine thiothixene trazodone triazolam trifluoperazine trimipramine venlafaxine zolpidem
Other Related Drugs chlorhexidine gluconate probenecid	ANTI-DIARRHEALS diphenoxylate HCL, atropine sulfate loperamide octreotide acetate paregoric tincture of opium	PSYCHOTROPICS alprazolam amitriptyline bupropion buspirone butabarbital chloral hydrate chlordiazepoxide w/w/o clidinium chlorpromazine clomipramine clonazepam clorazepate clozapine desipramine dextroamphetamine sulfate
		Anticonvulsants carbamazepine divalproex sodium gabapentin magnesium sulfate phenytoin primidone valproic acid

NOTES:

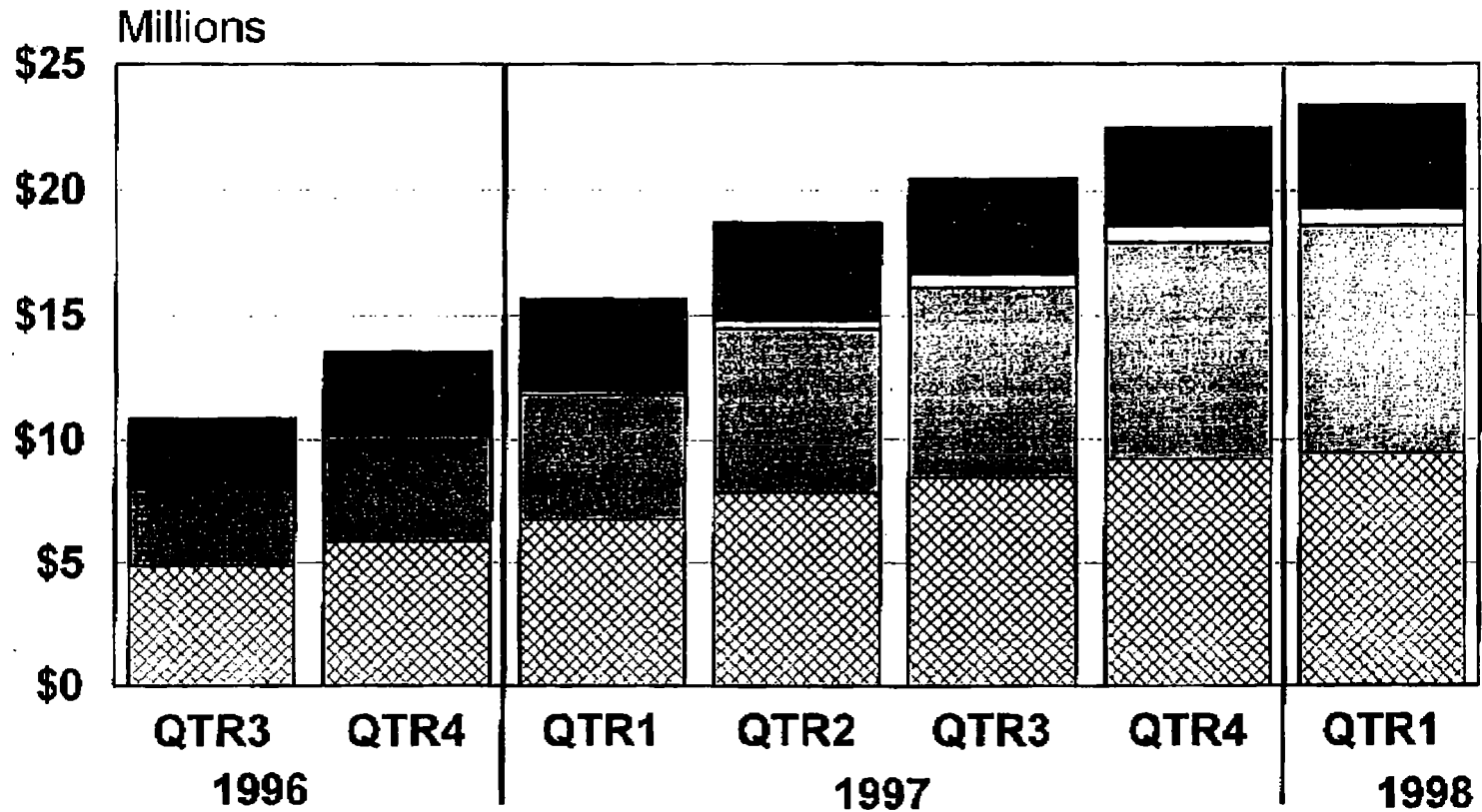
@ Methadone is available only for pain relief; ADAP does not cover methadone maintenance.
ADAP covers all prescription strength forms and brands of the Formulary drugs, unless otherwise indicated.
Additional antibiotics are listed for HIV/AIDS indications on the Formulary - Page 1.

ADAP Active Enrollment



New York State ADAP Costs Expense by Quarter

July 1996 through March 1998





LOG CABIN EDUCATION FUND

AIDS POLICY INSTITUTE

Need

In keeping with the mission of the Log Cabin Education Fund, an organization dedicated to educating the American public on gay and lesbian issues, there is a need for policy research and development which bridges the gap between the community directly affected by HIV/AIDS and the more conservative sectors of the American public. To fill this need, the LCEF AIDS Policy Institute was formed.

Purpose

To study, research and provide analysis of national AIDS policy issues involving basic research and drug development, regulation, care funding and reimbursement and patient rights. The LCEF AIDS Policy Institute shall emphasize conservative and mainstream analysis of these areas of study on national AIDS policy, and policy positions shall be based on the fundamental principles of individual rights, personal responsibility, and free-market solutions.

Projects

As it studies and develops AIDS policy positions, the Institute's primary focus is on:

MEDICAL CARE: The increasing need for funding and program development to provide medical care for people with AIDS requires intensive study and analysis of Medicaid, the Ryan White CARE program, and other funding programs, especially the AIDS Drug Assistance programs. As the Republican Congress reforms government, pro-patient study and input will be vital to the process. The Institute is a leading consultant on AIDS medical care funding policy in the U.S. Congress, in which saving and lengthening the lives of people with HIV/AIDS must be the top priority of the national AIDS strategy.

FDA REFORM: People with HIV/AIDS are in desperate need of increased access to new drug therapies, and the FDA has too often placed regulatory obstacles in the way of people with terminal illnesses such as AIDS. The Institute was the only gay organization in the nation advising Congressional leaders who crafted recent FDA reforms which passed the 105th Congress with overwhelming bi-partisan support.

FREE MARKET MEDICAL INNOVATION: The Institute believes that the eventual cure for AIDS will be developed in the private sector. Every life-saving, breakthrough HIV/AIDS drug has been developed in the free market, for-profit private sector. Promoting free market incentives for

HIV/AIDS drug development, educating the public on recent private sector medical breakthroughs in HIV/AIDS treatment, and studying their impact on public policy is the goal of the **Free Market Medical Innovation Project**.

Vision

A NEW PERSPECTIVE. From its unique perspective, with strong ties to both the conservative movement and the communities greatly affected by the HIV/AIDS epidemic, the Institute is charting a new course for HIV/AIDS policy -- with changing solutions for a changing epidemic.

The Institute shall work closely with other policy organizations, elected officials, leaders in the health care and pharmaceutical industries and other concerned Americans seeking to bring a fresh perspective to HIV/AIDS policy.

**For more information about the
LCEF AIDS Policy Institute**

**1633 Q St., N.W. #210
Washington, DC 20009**

(202) 347-5306

**Richard Tafel, President, Log Cabin Education Fund
James P. Driscoll, Ph.D., National AIDS Policy Advisor**