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BPHC Bureau of Primary Health Care

4350 East West Highway, Bethesda, MD 20814
(301) 594-4110 • fax: (301) 594-4072
http://www.bphc.hrsa.dhhs.gov

The People We Serve...The People We Are

Fact Sheet

DRUG PRICING PROGRAM

The Office of Drug Pricing (ODP) is responsible for implementing and managing Section 340B of the Public Health Service (PHS) Act.

MISSION

ODP's Drug Pricing Program enables entities covered by this Act to access discount prices for covered outpatient drugs and to maximize their participation in the program. ODP supports BPHC's strategic plan for systems development to sustain and manage growth of primary health care delivery systems.

ACTIVITIES

ODP provides guidance, technical assistance, and liaison services for the drug discount program among: 1) Federal, State, and local government agencies involved in health care, including State Medicaid agencies; 2) the pharmaceutical industry; and 3) eligible health care delivery sites. Activities follow.

- Administer PHS agreements with drug manufacturers and work with the Health Care Financing Administration (HCFA) concerning manufacturers' continuing Medicaid eligibility.
- Manage database of eligible and participating entities.
- Implement and manage the Prime Vendor Program.
- Manage program for Disproportionate Share Hospitals.

ACCOMPLISHMENTS

ODP's success is often measured in terms of participating covered entities. The number of participating entities increased from 4,545 in 1995 to 6,254 in 1996. Participating entities save pharmaceutical costs, freeing resources to improve therapeutic outcomes for their patients. FY 1996 accomplishments follow.

- Update Entity Database quarterly—to transmit to HCFA and manufacturers.
- Maintain file of 526 PHS manufacturer agreements, including 11 new and 2 terminated in FY 1996.
- Published Prime Vendor draft solicitation in the *Commerce Business Daily*, advertised final solicitation, and will select Prime Vendor to begin operations during FY 1997.
- Implemented a certification process for 170 Disproportionate Share Hospitals.

- Participated in over 100 meetings among industry, covered entity, professional, and State Medicaid organizations; and provided more than 20 briefings to BPHC, HRSA, CDC, IHS, and the Office of the Secretary about the Drug Discount Program.
- Resolved over 500 informal disputes among industry, covered entities, and government programs involved in the drug discount program.

COLLABORATIVE LINKAGES

ODP exchanges information to administer the Drug Pricing Act. Peer collaborators include:

- BPHC: Office of Community and Migrant Health and Office of Special Populations
- CDC: TB and STD State block grant programs
- HCFA: Medicaid Bureau and Disproportionate Share Hospitals
- HRSA: Ryan White Care Programs and MCH's Hemophilia Program, HIV Services, and Maternal and Child Health Programs
- IHS: Urban Indian and Self Determination (P.L. 638) programs
- PHS: Office of Population Affairs.

Collaborative relationships also exist with:

- National Association of Community Health Centers
- National Alliance of State and Territorial AIDS Directors
- National Hemophilia Foundation
- Public Hospital Pharmacy Coalition.

APPROPRIATIONS

ODP receives BPHC program support funds.

FUTURE CHALLENGES

ODP's goal is to encourage and enable all eligible covered entities to participate in the Drug Pricing Program. Implementing the Prime Vendor Program will facilitate further negotiated price reductions, assisting covered entities to provide health care services for vulnerable and underserved populations.

For more information contact:

Office of Drug Pricing Program
Bureau of Primary Health Care
4350 East-West Highway, Room 10-2A2
Bethesda, MD 20814
301/594-4353 or 1-800/628-6297 301/594-4982 FAX
http://www.bphc.hrsa.dhhs.gov/odpp/drugl.htm

rev. 12/96

U.S. Public Health Service

Office of Drug Pricing

East-West Towers
10th Floor
4350 East-West Highway
Bethesda, MD 20814
(301) 594-4353

BPHC BUREAU OF PRIMARY HEALTHCARE

THE PHS DRUG PRICING PROGRAM

A BRIEFING BY THE DIRECTOR,
OFFICE OF DRUG PRICING,
BUREAU OF PRIMARY HEALTH CARE

U.S. Department of Health & Human Services

HRSA

Health Resources & Services Administration

Overview

- Section 602 of the Veteran's Health Care Act, which created Section 340B of the Public Health Service Act, provides discounts on outpatient drugs to certain "covered entities," PHS-assisted clinics and some "disproportionate share" hospitals
- Drug manufacturers must sign agreements with the Secretary of Health and Human Services as a condition for continued participation in the Medicaid program

The Covered Entities

- PHS grantees:
  - Community health centers
  - Migrant health centers
  - AIDS clinics and drug purchasing programs
  - Homeless clinics
  - Black Lung clinics
  - Public Housing clinics
  - Hemophilia treatment centers
  - Native Hawaiian health centers
  - Urban Indian clinics
  - Some family planning clinics

The Covered Entities (cont.)

- PHS sub-grantees:
  - Most family planning clinics
  - STD clinics
  - Tuberculosis clinics
- Community health center "look-alikes"
- Disproportionate share hospitals carrying out State and/or local government health care programs

Covered Entities, Eligible and Participating

		Eligible	Participating
HRSA	Community Health Centers	1,821	539
	Migrant centers	283	103
	Homeless centers	185	81
	Other health centers	63	26
	Ryan White	516	175
	Hemophilia centers	179	58
OPHS	Family Planning	5,094	4,897
CDC	TB	1,424	211
	STD	914	257
IHS	638 contractors	399	41
	Urban projects	45	12
NON PHS	FQHC (look-alikes)	266	63
	DSHs	288	176
	Total	**11,477**	**6,639**

Reasons Why Some Entites Do Not Participate

- No outpatient pharmaceutical program
- Low volume of prescriptions
  - Drug whole sale minimum $4,000 per month
- Only parts of system eligible, not all
  - E.g. TB and STD programs in a health department
- Making more dollars on Medicaid reimbursement
- May require costly systems change
  - Administrative burden or data collection
- Lack of a covered entity prime vendor

Drug Diversion

- Discounted outpatient drugs may not be:
  - Resold or otherwise transferred to persons who are not patients of the entity
  - Transferred to non-covered parts of a larger facility
  - Used in excluded services, such as inpatient care
- Separate purchasing and dispensing records are encouraged

Contracted Pharmacy Services
Federal Register Notice 8/23/96

- A "ship to-bill to" procedure may be used
- Contractor provides all pharmacy services
  - E.g. dispensing, record keeping, drug utilization, patient profiles, counseling
- Discounted drugs cannot be resold or transferred
- Medicaid prescriptions should not be contracted unless there is an arrangement with the State Medicaid Agency to prevent duplicate discounts
- Contractor should establish and maintain a tracking system to prevent diversion
- Covered entity and contractor may be audited

Patient and Entity Eligibility
Federal Register Notice 10/24/96

- An individual is a "patient of an entity" only if:
  - The covered entity has established a relationship with the individual such as maintaining records of the individual's health care
  - The covered entity provides health care services to the individual by health professionals who are either entity employees or under contract
  - The individual is registered in a State-operated AIDS drug purchasing assistance program

Prime Vendor

- Section 340B requires the Secretary to establish a prime vendor program under which covered entities may enter into contracts with a prime vendor for the distribution of covered outpatient drugs
- ODP's goal is to establish a prime vendor program which provides both distribution and price negotiating services
- ODP is examining two options:
  - A HRSA solicitation to select a prime vendor
  - An agreement with another Federal agency to use their prime vendor arrangements for the covered entities

Electronic Data Retrieval System (EDRS)

- The EDRS provides a wide variety of downloadable information about the Drug Pricing Program, 24 hours a day, 7 days a week:
  - Searchable data files on the covered entities and drug manufacturers
  - All proposed and final Federal Register Notices
  - Frequently asked questions and answers (FAQs)
  - Formulas for pricing calculations
- EDRS can be reached at (301) 594-4992 using a PC with a modem and terminal emulation program (e.g. Procom or Crosstalk) or at http://www.bphc.hrsa.dhhs.gov/odpp/drugl.htm using a web browser

Health Care Trends

- Mergers of health care delivery systems
  - **Health Maintenance Organizations**
  - **Hospitals**
  - **Home Health Care**
  - **Urgent Care**
  - **Ambulatory Care**
- Federal Acquisition Streamlining Act
- Welfare Reform
- State Medicaid Waivers

JUL. 8.1997 9:48AM GLAXO WELLCOME

FAX from: **LINDA GRINBERG**

From FAX #: (310) 471-4565 No. of pages: 3
To: Daniel Montoya & Sandy Thurman FAX # 202-632-1074
Company White House - AIDS Office Date: 7/8/97
Remarks

GlaxoWellcome Fax

Health Care Coalitions

To	Distribution	Fax	
From	Jennifer McMillan	Date	07/08/97
Telephone	919/483-2392	Total Pages	3
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Mission

Glaxo Wellcome is a research-based company whose people are committed to fighting disease by bringing innovative medicines and services to patients throughout the world and to the healthcare providers who serve them.

Values

High Standards
Valuing Customers
Valuing People
Teamwork
Embracing Change
Achievement
Corporate Citizenship

Glaxo Wellcome Inc.
Five Moore Drive
PO Box 13398
Research Triangle Park, NC
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Telephone
919/483-2392

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GlaxoWellcome

July 8, 1997

TO: 1592 Access Coalition
FROM: Jennifer McMillan
Director, Health Care Coalitions and Advocacy Relations
Glaxo Wellcome Inc.

CC: R. Ingram, P. Young, S. Lafon

Thank you for your letter of June 16.

We wish to reiterate our commitment to provide 1592 to as many people as possible through compassionate use and expanded access protocols. Your letter called for three stages of access: compassionate use, expanded access and accelerated approval. As you know, our plans have long included this tiered approach to access.

As we have discussed, we encountered a problem with the physical form of the drug substance last summer, which resulted in some delays while a new alternative salt was identified, scaled up into the pilot plant and transferred into full scale production. We will have additional quantities of 1592 early in 1998, but in the meantime, the drug supply we currently have available is limited.

We have addressed the concerns outlined in your letter below. In addition, we will convene a teleconference to address your questions from 1 p.m. to 2 p.m. EDT on July 9. If you have not received information about the call, please contact Michael Joyner at (919) 483-2987.

Compassionate Use

In order to provide a limited supply of drug to as many people as possible, we have developed a plan to "pace" enrollment into the compassionate use program in the United States. This will allow us to provide 1592 to approximately 2,400 patients in the US, which is twice as many people as was previously projected. (Our initial proposal was for a non-paced program which would provide 1592 to 2,000 patients worldwide, with drug for 1,200 patients allocated to the US.) We believe that this measured approach of enrollment will also allow us to provide the participating sites with emerging data on this therapy, which will help physicians evaluate which patients are likely to benefit from 1592. As a result, the sites should be able to effectively triage their patients.

Glaxo Wellcome is committed to sustaining supply of 1592 to each person who enters the compassionate use program as long as the person is responding and tolerating the drug (until accelerated approval is achieved.)

We will review the responsibilities of the regional sites with the study coordinators. The participating sites are aware of their role to accept referrals from other practices. We will periodically query sites for that information.

Glaxo Wellcome Inc.
Five Moore Drive
PO Box 13398
Research Triangle Park
North Carolina 27709

Telephone
919 248 2100

There are now more than 65 US sites for the compassionate use program. We believe it is important that patients receive 1592 from physicians who have some experience with this experimental drug, and it is essential that we collect safety data on patients in this program. As a result, we cannot commit to providing access outside of the regional sites. The use of regional centers will be re-assessed prior to initiating the expanded access program in 1998.

Expanded Access

Assuming that the production scale-up continues without unexpected delay and that no safety and efficacy concerns from the controlled studies or the compassionate use programs emerge, we will be able to move into a more traditional expanded access program in March of 1998. Although the criteria for our expanded access program are not yet finalized, we anticipate being able to accommodate a cumulative total of over 13,000 people worldwide on an expanded access basis. This figure includes approximately 4,000 people who will receive 1592 on the open label programs this year and for whom 1592 will continue to be available through expanded access next year.

Protocols and Clinical Trial Sites

A number of protocol outlines and site lists have already been distributed, and we will continue to provide these as the studies and site lists are finalized.

Accelerated Approval

We are in active discussion with the FDA regarding the development of 1592 and we will provide the community with updates on that process when significant new information is available. We are pleased to be able to expand the use of 1592 at such an early stage in the drug's development. As you know, these initiatives are significantly earlier in the development process than the access programs for any other HIV treatment.

Finally, we believe it is important to re-emphasize our commitment to the development of 1592. Glaxo Wellcome has every incentive (medical, ethical, economic) to diligently pursue development of 1592 and we are working hard to do this in a manner that can clearly demonstrate the safety and efficacy of the drug.

We look forward to answering any questions you may have regarding these initiatives.

MEMO

SLT - some notes on the conference call

To: Sandra L. Thurman

From: Daniel C. Montoya and Sheldon E. Gilbert

Subject: GlaxoWellcome-FDA-1592 Access Coalition Conference Call

DCM

1592

Date: July 11, 1997

Attached are the minutes from the teleconference call held between all parties enumerated above held yesterday, July 9, 1997 from 1:00-2:30 pm EDT. The conference convened to address a letter that had been sent out by Jennifer McMillan, Director of Health Care Coalitions and Advocacy Relations at Glaxo Wellcome in a response to a letter that had been sent to her on June 16, 1997.

In their letter, Glaxo Wellcome restated its commitment to provide 1592 to "as many people as possible through compassionate use and expanded access protocols." Before beginning to address their definitive plans to establish such programs and policies of compassionate use and expanded protocols, GW gave a brief explanation of the 1592 delay in development claiming that it was due to problem with the physical form of the drug that had been discovered last summer.

Compassionate Use. GW plans to develop a "pace" enrollment into the Compassionate Use Program in order to provide "a limited supply of drug to as many people as possible". Plans to provide 1592 to approximately 2,400 patients in U.S. (apparently twice as many people as was previously intended considering how the original plan was for a non-paced program which would provide 1592 to 2,000 patients worldwide, with drug for 1200 in US). This "pace" program would allow for 100 patient per week enrollment. In addition, GW stated its commitment to sustaining supply of 1592 in each patient who is enrolled in program as long the person is responding and tolerating drug.

Are intent of collecting data from numerous physicians who have extensive experience with the experimental drug from all of their 65 sites for compassionate use programs in the US. But GW claimed that they could not extend themselves by providing 1592 outside of their designated sites.

Expanded Access. GW claimed that if all goes well with production scale-up and there are no safety and efficacy concerns that begin to emerge, then they will be able to move into " a more traditional expanded access program in March of 1998". Although criteria for expanded access have yet to be finalized, GW anticipates being able to accommodate a "cumulative total of over 13,000 people worldwide on an expanded access basis." This however, would include nearly 4,000 people who will receive 1592 on the open label programs for this year and the one following.

Protocols and Clinical Trial Sites. GW has apparently distributed a number of protocol outlines and site lists that it will continue to provide.

Accelerated Approval. GW made clear that active discussion with FDA about the approval of 1592 are still on-going and that it will provide the community with updates on the drug's development and approval process.

The conference call that was held soon after the distribution of GlaxoWellcome's letter was a highly contentious and often times emotional discussion that centered around much of what the Coalition considered to be often inconsistent and duplicitous information or misinformation rather. There was much debate of the original figures of 20,000 - 30,000 patients that the Coalition felt GW had firsts agreed to in their proposed Compassionate Use and Expanded Access programs. Many of the Coalition members felt that they simply were not being told the full story about 1592. For if it had received FDA approval in such early stages in its development then there should be little cause for the delay in its distribution.

1592 Access Coalition

Conference Call: Wednesday, July 9, 1997

Jeff Getty moderated this conference call between GlaxoWellcome (GW), the FDA and the 1592 Access Coalition.

I. FDA

As a preface to any discussion of the drug, 1592, between the Coalition and GW, the FDA, when asked by the Coalition whether they needed more reassurance that the drug met federal safety guidelines, they quicklymade it quite clear that to their knowledge the drug had been approved.

Representatives of the FDA then began commenting on some of the logistics of the expansion of Compassionate Use Programs and Expanded Access Programs, addressing some of the problems that many companies may encounter in their attempt to increase treatment programs with particular focus on how management relates to standard access. The FDA commented that often times supplies that are needed for standard access are taken from those that are designated to clinical trials. Secondly, small companies that are on the verge of marketing encounter distributing problems (i.e. small batches).

Note: *Although 15 minutes had been allotted for discussion with the FDA, all matters were succinctly addressed in only the first 5 minutes of the conference.*

II. Compassionate Use Program

A. *GlaxoWellcome Commitment:*

When asked by one of the Coalition members to state their commitment before all those present to use their "best efforts" to increase the size of treatment programs if additional drug becomes available, representatives of GW refused to make such promises or commitments. They claimed that limitations based on production costs in addition to inadequate data on 1592 (as it is still in early stages of production) would make the expansion of such programs "unjustifiable". As they put it, they "simply are not ready to make such a commitment".

B. *Triage*

A triage, established by one of the members of the Coalition had been described and was met with little discussion afterwards. Apparently it had already been discussed and approved by the Coalition prior to the conference, and it was being presented to GW for the first time. The stipulations for the Triage were as follows:

1. If the patient's health is rapidly declining
2. If the patient's health is undergoing slow/moderate decline but is still able to wait
3. If the patient's health is stable and is still able to wait a couple of months

C. Distribution Off-site/On-site

There was some concern on the behalf of the Coalition on the accessibility to the 65 sites for Compassionate Use Programs that GW has apparently develope to mant of its patients. One Coalition member who has just learned that in order to facilitate site accessibility in Canada, GW reimburses the travel expenses of patients who either live in rural areas or are too ill to travel and require special services, wanted to know if similar steps will be taken in the United States.

Representatives of the pharmaceutical company stated that they intended to have in place a similar program once there was enough data to support the expansion of larger programs in 1998. They then closed by saying that they will have to determine the ability to fund such a travel reimbursement program in the United States at some later date----but no definitive answer was given, in fact one of the representatives of GW claimed that he never knew of the existence of such a program in Canada.

D. Pediatric and Dementia Allocation

One coalition member concerned about the 2,000 patient figure reported in a letter from GW on July 8, wanted to know whether pediatric and demented patients were accounted for in such a figure or any of their other figures for that matter.

One representative of GW stated that the patients that are being referred to, have in no way been forgotten as insinuated by the coalition member who had raised the point. They were simply not included in the 2,000 patient figure because it was believed that it had already been understood. "There are 2,000 patients world-wide for the Adult Program (of which 1200 will be in the U.S.), 200 pediatric patients and 200 demented patients."

There seemed to be a great deal of uncertainty over these figures and was a great source of contention throughout a large part of the conference. One representative from GW claimed instead that there would be 250 and not 200 pediatric and demented patients respectively.

E. Equity of Access

There were some concerns on the part of the Coalition on the extent to which preferential treatment would preclude the equitable distribution of medicine in many of these planned sites. Thus feeling that such concern warrants strict regulation, the Coalition asked GW to commit itself to seeing that such mechanisms are placed to ensure the equal patient access to 1592.

GW responded by ensuring the Coalition that they will do their utmost to have in place such a community-based corrective mechanism by communicating with investigators, but doing so may prove difficult due to patient anonymity.

One Coalition member stated his complete dissatisfaction for GW's efforts and contended that a more aggressive approach would be needed and was willing todiscuss the placement of a more

austere program with GW at some later date.

III. Expanded Access Program

A. Unresolved Patient Figures

The greatest source of contention between the Coalition and GW was over some of the patient figures that, according to nearly all of the members of the Coalition, were always changing. The discussion over the inconsistency of GW's patient figures first began with a recommendation by one Coalition member that the GW provide regular weekly/monthly progress reports on such programs (i.e. the number of patients that apply and are approved/disapproved).

One representative of GW questioned the necessity of such regular progress reports.

This was quickly met by a response from one of the Coalition members who argued that such reports are intrinsic components that are put in place to safeguard the rights of patients and ensure the maintenance of their needs.

This soon led to a heated debate on the ethical nature of much of GW's marketing policies of 1592 over the past few months. Many of the Coalition members felt that GW simply "was not being honest". They expected patient figures to range from 20,000-30,000 and not, as they felt, the wholly unacceptable figure of 8,000-9,000 patients. Some members of the Coalition voiced great concern over GlaxoWellcome's apparent breach of the original agreement to have 5,000 patients worldwide enrolled in the Compassionate Use program to what is now 4,000 patients worldwide. As a result, the "pacing" procedure would now only allow for only 100 patients enrolled in the Compassionate Use program every week as opposed to the the original 200 patients per week.

In trying to understand what may have possibly led GW to come up with such figures, members of the Coalition were quite skepticalabout the claims made by GW that product capacity played a large part in limiting these numbers

GW maintained that they came up with such figures based on a number of factors, among them data from the CDC and estimated costs for clinical trials.

One member of the Coalition contended however that it was quite possible to sustain Expanded Access programs while still running clinical trials.

One representative of GW then proceeded to passionately restate her company's commitment to eradicating this disease and felt that GW had been nothing less than "honest" throughout this entire process with members of the community. But her statements were soon met with a great deal of vitriol and critique that was fully played out at the end of the conference with the personal statements made from each of the Coalition members to GW.

B. Availability

Although the Coalition remonstrated the March deadline for the availability of 1592, GW maintained that they can not do anything earlier than the first quarter of 1998.

One member of the Coalition strongly advised GW to take heed of the proposed Triage to ensure that those patients who really deserve the drug will receive it.

GW then added that they plan on changing the Compassionate Use Program from a center-based program in 1997 to a non-center-based program in 1998.

IV. Follow-up Meeting

A. The date for the next meeting was not able to be set and will be taken up at some later time with individual parties.

B. Established that the developments of 141 will need to be on the agenda for the next meeting.

C. Established that the size of and inclusion/exclusion criteria of expanded access programs needed to be readdressed.

V. Personal Statements/Summations by Coalition Members

Eileen Mitzman: *"I do not understand why a company of this size feels so limited. I want GW to understand that my daughter died of this disease because she wasted. I want GW to know that everyday they wait another person dies of this disease!"*

Andy Lipshick: *"When is GW going to enroll its first patient in its Compassionate Use Program?"*

GW: "We do not know as of yet. Sometime in July."

Andy Lipshick: *"When in July?! We are already in July!"*

Paul: *"Of the 65 sites how many have received approval for IRBs?*

GW: "We do not know."

Steve: *"How will GW ensure that non- preferential treatment will not occur?"*

John James: *"To what extent do small batches have to become approved?"*

Teo: *"I am convinced that GW doesn't have the drug to expand the program. If they really had the drug then they would have had approval sooner! Perhaps the drug is not working*

and they don't want to admit it! They want to control any possible negative buzz! But this doesn't resolve GW of its responsibilities of getting the drug to those who still desperately need it and have no other options."

Lee Jones: *" I am a member of a small support group in Northern California and I just want GW to know that four of our members (children) will not make it to your March 1998 deadline."*

_____: *"I feel that GW is making a mockery of Compassionate Use Programs!"*

Peter Cashman: *"GW has to do its best to ensure that there is equity in access and equity in treatment."*

_____: *"GW needs to take heed of some of the lessons learned by some of its biggest competitors. Bristol Meyer is still benefitting from its generosity while LaRoche is still suffering from its standard access policies. GW needs to go back to the drawing board."*

Marty: *"I am less enamored with 1592 than others. GW has changed for the worst over the past few years. It has new people that are grossly mismanaging the company. So many of its best scientists have already left the company."*

_____: *" I am very discouraged with GW. Seven members of my own group were even arrested in their New York corporate offices."*

_____: *"Likewise I am also disappointed about the extent to which GW has done little to address the issue of pediatric patients and as well as patients with dementia. Secondly, either this company underestimates the intelligence of the people with whom they are dealing with or they have crafted a very clever marketing plan---I would venture to say the latter--just admit it GW!"*

David Gillman: *"Certainly the development of 1592 and 141 has been an extremely slow process when compared to saquinavir. GW also needs to realize that enrollment problems (i.e. over-saturation) do not always occur. It didn't happen with 3TC. GW should have an unlimited access program."*

Mrs. Greenberg: *"I think that we all need to keep in mind that we are here to stay in touch with our humanity. GW's ability to eliminate nearly 11,000 people from Expanded Access programs with the arbitrary stroke of a pen is a travesty!"*

NOTE: Some of the statements above made by some of the members of the Coalition are not direct quotes. They were in large part paraphrased with the intent of making them as close to the original statements as possible.

Sandra Thurman

TO: Daniel Montoya
Nat'l Office of AIDS Policy

FAX #: (202) 632-1096

FROM: James Learned

OF PAGES: 6
(including cover)

CALL 212/255-0520 IF THERE IS A PROBLEM WITH TRANSMISSION.
FAX RESPONSES TO 212/255-2080

[redacted]
150 W. 26 STREET, SUITE 201
NEW YORK, N.Y. 10001

PWA HEALTH GROUP

[redacted]
(212) 255-0520
Fax: (212) 255-2080

Date: September 19, 1997

To: HIV/AIDS Community Colleagues & Friends

From: James Learned, PWA Health Group

Re: 1592 & THE TORTURED JOURNEY TO ACCESS
A MODERN MORALITY TALE

One year ago, I thought Glaxo Wellcome's nucleoside analogue, 1592 (Abacavir), was one of the most exciting new drugs in the pipeline. Now, a year later, I'm much more wary of 1592's potential and have just turned down an invitation to a private meeting with Glaxo representatives at their United States headquarters in North Carolina. It's been a tough year, and my experience working to help get 1592 to people has raised a lot of confusing questions. I hope that what follows can help us talk to each other about where we are and where we're going with treatment activism.

Community Efforts

Last Fall, community folks began asking Glaxo for a 1592 compassionate use program. A *Wall Street Journal* article in early November, criticizing Glaxo for not having a program in place, was immediately followed by a community consensus statement (from the 1592 Access Coalition) demanding a two-phase expanded access program to begin "without delay." Three months later, in February, Glaxo released a brief reply: "The first compassionate use of 1592 will be a program for children which is scheduled to begin within the next three months." In fact, an extremely limited pediatric program opened *nine* months later (*250 kids worldwide*). From the beginning, the community made it clear that Glaxo's plan was far too small. But throughout this year, Glaxo has played an ugly numbers game. First they said they'd make 1592 available to 2,500 people worldwide as of July. Then the number grew to 5,000 people -- not that they were really making more drug available, they'd just give it out slower, allotting it to 200 new people a week from August through December. Meaning that the PWAs who would finally get drug the week of December 22nd were included in that 5,000 person number for 1997. The numbers game confused most of us while implying twice as large a program.

[redacted]

In fact, since the compassionate use program design was "officially" announced in April, the amount of 1592 offered by Glaxo has remained completely unchanged. The design is the worst I've seen. The result today is that 1592 is available to 100 people a week through only 60 sites in the whole country! This means, in practice, that doctors at each site can choose one of their hundreds of patients each week -- leaving everyone else who needs 1592 out in the cold.

Production Problems, My Ass

Glaxo has cited "production problems" as the main reason for this tiny program. Production excuses have been used before, most notoriously by Merck, Abbott and Roche in last year's protease nightmare. I think too many of us have been willing to buy this excuse. Personally, I don't think it's the role of the community to validate a lousy company plan, whatever the company's excuses. I don't care about Glaxo's supposed production problems! Glaxo is the largest pharmaceutical company in the world, one of the largest companies *of any kind* in the world, a company intimately familiar with the idea of subcontracting and planning for demand. If they wanted to, they could subcontract 1592 today. 1592 is similar to 3TC -- it just ain't that hard to make. Furthermore, Glaxo could make more of it immediately available by using stock they're holding to determine shelflife, like other companies have in the past. If there is a real supply problem, it's simply because the company doesn't want to make enough drug to supply a real compassionate use program.

Right now, they're deciding how much drug they'll make available for a second, larger expanded access program in 1998. They said this would open in January; now it's mysteriously moved to March. This summer, Glaxo projected being able to serve 8,000-9,000 people through this second program in '98, about 5,400 of them in the United States. This number is way below what everyone thinks is needed, even Glaxo.

Glaxo Feels Our Pain

Glaxo has shown no interest in hearing, let alone addressing community concerns. There have been protests and street actions in New York, San Francisco and Toronto. New York's City Council and San Francisco's Board of Supervisors have publicly demanded that Glaxo enlarge the programs. Articles in HIV newsletters have denounced Glaxo and the program design. Meanwhile, representatives from Glaxo's "Health Care Coalitions and Advocacy Relations Department" (named, I'm afraid, with no sense of irony) have had private conversations with individuals in which they avow their commitment to address community concerns, while at the same time giving each person conflicting information. On July 9, Glaxo reps participated in the only conference call the company has agreed to, largely in response to pressure from the Office of AIDS Policy in Washington. It was the most frustrating conversation I've had with a drug company. The reps were unable or unwilling to respond to any of the specific questions and ideas which had been sent to the company a month earlier and widely published in national newsletters. After hearing the anger, frustration and disappointment voiced by the many community people on the call, the company refused to meet with anyone "for the

time being". Meanwhile, the tiny first program outlined by Glaxo in April finally opened in August, with press release fanfare and absolutely no changes in numbers or entry criteria.

Following the July conference call, I spoke with Linda Grinberg, a good buddy who spearheaded much of the work of the 1592 Access Coalition. We discussed the likelihood that Glaxo would stall a couple of months and then invite a handpicked group of community people to meet in private, listen attentively, and rubber-stamp the 1998 expanded access plan, as has happened so often with past programs. I fantasized a scenario in which people would boycott the meeting, forcing the company to deal publicly with the very real, large and diverse community of PWAs who desperately need 1592, rather than only those who relish the proverbial place at the table. I felt very high and mighty, sure of my position as a model of integrity.

An Invitation!

During the last week of August, while many of the 60 compassionate use sites still weren't open, I and seven others who work on treatment access issues received an invitation to be flown down to Glaxo's offices in Research Triangle. The company wanted to discuss "development plans for 1592 and 141 (Glaxo's upcoming protease) ... and to initiate a dialogue between the company and the community as we begin to define the larger expanded access program." The "initiate a dialogue" phrase was particularly bizarre considering all the calling, writing and faxing that people had been doing all year to no avail.

I was surprised since I'm not accustomed to being invited to the private meetings that are so common between treatment "activists" and pharmaceutical companies. In general, I don't like the concept of private meetings. The cruel lotteries and vastly diminished expanded access programs of the last few years are, I believe, the direct and sorry result of private meetings. Look at how few people received Saquinavir, Norvir or Crixivan from those hideous lotteries that community members helped devise. Community members involved in private meetings have the best intentions. But not even the brightest and most aggressive advocate can represent "the community" -- the true HIV/AIDS community is far more diverse, interesting and full of passion and ideas than a few seasoned treatment activists can ever be. And besides, the reality is that every time we meet with a company, it's used against us. The way community involvement is exploited is repulsive. In the case of 1592, after a year of hostile phone calls and meetings, Sir Richard Sykes, Glaxo's CEO in London, writes to investors and PWAs alike: "we are working with ... members of the HIV community around the world." He implies that we're satisfied -- an ugly distortion of our honest attempts to help create useful programs.

Rationalizations

So I received my invitation from Glaxo with a mixture of confusion and heightened responsibility. My immediate reaction was to refuse it. But when I talked with other

people, advocates as well as individuals who really *need* 1592, my resolution wavered. I began to wander down the path taken by all of us -- including myself -- who have ever attended exclusive meetings. What if Glaxo is at last interested in listening to our concerns? What if *I'm* able to articulate those concerns in a way that's both aggressive and clear? If I decline the offer, Glaxo will say that they invited the community to "dialogue" and the community refused to talk. Damned if I do, and damned if I don't. After all, it's not as though they can buy me, compromise my integrity, or change my conviction that 1592, whatever its merits, must be available to whoever needs it. And besides, it's just one meeting. And in North Carolina! It's not like I'm heading off for a weekend in San Francisco or Paris!

Time to Pull Back

For an entire year, Glaxo has refused to listen. They have refused to change their programs in any way. They've treated the community with contempt. This is the company whose price-gouging on AZT in 1987 will live forever in the memory of those of us who are still around. **And** the company that raised the prices of AZT and 3TC last year when the drugs began to be more widely used in combinations. **And** the company that conducted the largest expanded access program in history (3TC to 32,000 people in 1995) based on less data than we have for 1592. Glaxo has boycotted two POZ Expos (New York and Washington, DC) for fear of having to face non-violent demonstrations by PWAs demanding 1592. The company has circulated internal memos about death threats and urged private security for Glaxo employees traveling to New York, creating paranoia and distrust based on nothing. The only thing Glaxo has to fear is the honest demand that they create ethical access to possibly life-saving treatment.

So I refused Glaxo's invitation. As did others. Whether the private meeting takes place or not will make no difference to how many PWAs get 1592 next year. After I declined the invitation, a Glaxo rep (sincerely or cleverly befuddled, who can tell?) called to ask me how the company could develop a good relationship with the community. The answer is simple: MAKE 1592 AVAILABLE TO THOSE WHO NEED IT. Glaxo has shown no good faith. Creating an ethical access program and releasing critical data would be a sign that the company understands its moral responsibility to people with AIDS. Until then, let the boycotts, the demonstrations, the letter-writing, telephoning and faxing increase in size, imagination and force.

Now What?

Community-corporate partnership doesn't work to our benefit -- ever. The pharmaceutical industry and people with HIV/AIDS have different goals -- sometimes overlapping, but different. The industry is about profit. We're about survival and health. We will always be adversaries who need each other. I'm almost overwhelmed with questions about the role of those of us who work on treatment access issues. As Martin Delaney of Project Inform has eloquently written, when do our attempts to get a new drug turn into more marketing for the companies? We've splashed 1592's name everywhere, creating enormous demand and unrealistic expectations. DMP266 (Sustiva),

Dupont Merck's new NNRTI, has received very little play, even though it may be a far more useful anti-viral. And those of us who talk to the drug companies, who are we accountable to? When the resulting programs are lousy, doesn't our involvement in their design inevitably discourage community outrage? Doesn't today's model of treatment demand new standards of inclusion for compassionate use programs? Why aren't we demanding data from these programs so that we know early on how the drugs work? And, maybe most important, why aren't we openly discussing and examining the current process of who gets chosen to represent the communities of people with HIV and AIDS? Can we do this without trying to destroy each other in the process?

Ethical and sound medical access to new treatments requires grassroots organizing, the polar opposite of private, elitist meetings where individuals represent "the community." We all have a part to play in this organizing work, and every voice needs to be heard.

1592: What Is It?

Glaxo Wellcome's new nucleoside analogue, 1592 (Abacavir), is now available to a few thousand people *worldwide* through the smallest, most abysmal "compassionate use" program ever. 1592 is no miracle drug; early trials have reported side-effects including up to 70% nausea. Test tube studies show that cross-resistance may exist between 1592 and ddI, 3TC and ddC, so it may not be useful to people who've already gone through these other nucleosides. Anecdotally, some folks with earlier exposure to these other nucleosides have had excellent if limited results with 1592, while others definitely haven't. But for someone who's anti-viral naive, 1592 may be the most potent nucleoside yet. But whatever its degree of treatment potential, 1592 must be made available to anyone who needs it. To apply for the compassionate use program, have your doctor call (800) 501-4672.

1592 ACCESS COALITION

To: Sandy Thurmond	From : Linda Grinberg	
Company: The White House, AIDS Czar	Telephone: 310-471-6565	
Fax Number: 1-202-632-1096	Fax Number: 310-471-4565	
Subject : Conf. Call/Demand Letter	Date: 6/16/97	Pages: 4

Sandy:

The attached formal demand letter began getting circulated to ASO's around the country for endorsement and will be sent to Glaxo, once we get a signficant number of organizations within the next week or two. It contains pertinent info that you should have at hand, as supply is certainly the main issue, but not the only issue we are concerned with.

Jeff is not feeling well and he's asked me to call your office to get an update from you on whether or not Glaxo has responded to you, and if so, to have your office fill me in. He's also asked me to make arrangements for our conference call follow-up conference call this week. Please get back to me on this at your earliest convenience, so I can set that up and telephone everyone in the group accordingly.

Thanks.

Best,

Linda

1592 ACCESS COALITION

To: Sandy Thurmond	From : Linda Grinberg	
Company: The White House, AIDS Czar	Telephone: 310-471-6565	
Fax Number: 1-202-632-1096	Fax Number: 310-471-4565	
Subject : Abacavir/1592	Date: 6/16/97	Pages: 4 3

Glaxo Wellcome has announced that it will shortly launch a compassionate use program for its new drug, commonly known as "1592". Activists throughout the nation who have worked with the company to develop this program feel it is inadequate to meet the need. The program offered thus far is severely limited in both size and compassion and will initially reach 2500 people worldwide. Plans for a larger expanded access program, also promised by Glaxo, have been delayed until the beginning of 1998, at the earliest.

By any standard, this is not good enough. The number of people with an immediate need for this drug continues to grow each week.

We need your support -- and that of your organization -- to improve upon this program.

While many people have shown clinical improvement with protease inhibitors, increasing numbers have now failed on all available combinations. Others have never been in a position to benefit because they lacked the other "new" unused companion drugs needed to make an effective combination therapy. People have simply run out of drug options. 1592 is the only new drug likely to become available in the near future to help those in the most desperate need. In preliminary testing, 1592 appears to be reasonably safe and highly potent -- perhaps 10 times more potent than AZT. It will make a critically needed addition to the arsenal of drugs needed to combat HIV.

We are asking you to join and support our efforts by adding the endorsement of your organization to the growing list of groups who have already signed on. We also ask that you circulate this fax and letter to other organizations as soon as possible. Every name adds to its strength.

If you have any questions or need more information about 1592 or the proposed program and why treatment activists find it inadequate, please contact Ron Baker at 415-543-4440. If you want to get more involved, please contact Jeff Getty at 510-653-6099. Please fax back your signed endorsements to 310-471-4565.

Time is of the essence. Thanking you in advance for your ongoing support and your prompt attention to this matter.

1592 ACCESS COALITION

June 13, 1997

Mr. Robert Ingram
Chief Executive Officer
Glaxo Wellcome, Inc.
5 Moore Drive
Research Triangle, NC 27709

Re: Development of Abacavir (1592)

Dear Mr. Ingram:

Community treatment advocacy groups and activists watch with growing concern as the major pharmaceutical companies continue to reduce the size of compassionate use and expanded access programs for promising new AIDS drugs. The limited 1592 compassionate use program proposed by Glaxo Wellcome provides the most recent example of the industry's misguided policy on early access.

The individuals and organizations listed below call on Glaxo Wellcome to take the following actions regarding 1592:

I. **Compassionate Use Program**
   - A. Commit to significantly increase the size of the compassionate use program scheduled to begin in July 1997. (It is anticipated that more than 10,000 patients worldwide may need 1592);
   - B. Triage patients to ensure those in most critical need are given highest priority;
   - C. Provide monthly progress reports to designated community representative(s) regarding production capacity and patient enrollment;
   - D. Describe procedures to ensure equity of access and avoidance of preferential treatment to patients at selected sites;
   - E. Provide the drug to patients who cannot access the medical sites designated by Glaxo. (Traditionally, compassionate use programs reach patients through their healthcare providers.)

II. **Expanded Access Program**
   - A. Initiate an expanded access program at the earliest possible date in 1997;
   - B. Provide details regarding inclusion/exclusion criteria, size and scope of program, distribution plans, and other pertinent information as soon as possible.

III. **Protocols and Clinical Trial Sites** - Provide information on 1592 protocols and identify clinical study sites, as promised, immediately.

IV. **Accelerated Approval**
   - A. File for accelerated approval of 1592 no later than March 1998;
   - B. Initiate rolling data submissions to FDA as soon as possible.

Promising new therapies such as 1592 must become available as soon as possible to people without treatment options who face disease progression or death. Community advocates and

activists call upon Glaxo Wellcome and all AIDS drug manufacturers to recognize that people with advanced disease have a basic right to speedy access to new experimental therapies when all other treatment options have failed.

We look forward to receiving your response to our concerns regarding 1592.

Sincerely,

1592 ACCESS COALITION

Ron Baker	David Gilden	Andrew Lipschitz, M.D.
Bill Bahlman	Linda Grinberg	Joel Martinez
Peter Cashman	John Iverson	Eileen Mitzman
Sally Cooper	Cleve Jones	Leigh Paidolfino-Danas
Paul Davis	Kate Krauss	Lili Rundback
Martin Delaney	James Learned	Matthew Sharp
Jeff Getty	Jules Levin	Theo Smart

Endorsements of AIDS Organizations:

ACT UP Golden Gate, Oakland, CA
AIDS Service Center, Pasadena, CA
Community Research Initiative on AIDS (CRIA), N.Y., N.Y.
F.A.I.R./Foundation for AIDS and Immune Research, Los Angeles, CA
Healing Alternatives Foundation, San Francisco, CA
N.A.T.A.P./National AIDS Treatment Advocacy Project, N.Y., N.Y.
Project Inform, San Francisco, CA
PWA Health Group, N.Y., N.Y.
San Francisco AIDS Foundation, San Francisco, CA
Treatment Action Group, N.Y., N.Y.

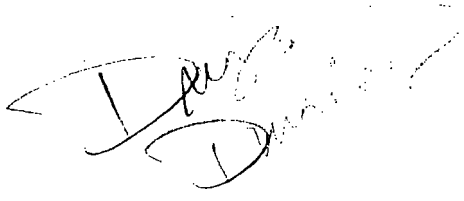
AGREED and ACCEPTED this ___ day of June, 1997:

By:_____ **Of:**_____
(Signature) **(Organization)**

Print Name:_____ **Phone:**_____ **Fax:**_____

cc: Jennifer McMillan
Steve LeFon

Sandy
FYI -
Important
DCM



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Facsimile 202 624-7222

www.pgfm.com

[DRAFT LETTER OPPOSING REPEAL OF COOPERATIVE PURCHASING PROGRAM]

Dear _____:

As an organization concerned about the affordability and accessibility of pharmaceuticals for HIV-infected persons, we are writing to ask your immediate assistance in opposing Section 323 of the Senate supplemental appropriations bill (S. 672). Section 323 would repeal the federal cooperative purchasing program established under Section 1555 of the Federal Acquisition Streamlining Act of 1994 (FASA).

We understand that, according to a recent study by the Prime Institute at the University of Minnesota, implementation of the federal cooperative purchasing program for pharmaceuticals could lower the cost of drugs, including those used to treat HIV, for public hospitals and state and local health departments by 25 percent or more. In light of the significant budget shortfalls of most state AIDS drug assistance programs and other government-financed HIV programs (including Medicaid), repeal of the cooperative purchasing program would harm both patients and taxpayers.

We also understand that both the General Accounting Office (GAO) and the General Services Administration (GSA) are currently studying the potential impact of cooperative purchasing as directed by Congress early last year. Because neither GAO nor GSA have completed their studies, the Congressional committees with jurisdiction over this program have not had an opportunity to hold hearings and receive comments from affected parties on all sides of this issue. Besides violating the constraint against legislating on an appropriations bill, Section 323 would effectively deny organizations, such as ours, any voice in the debate over the fate of this program.

For these reasons, we strongly urge you to oppose the inclusion of S. 323 in the supplemental appropriations bill.

Sincerely,

21452875.W51

Section 1555 of the Federal Acquisition Streamlining Act: Impact of Cooperative Purchasing on the Pharmaceutical Market

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and
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Acknowledgment: Financial support for this study was provided by the Public Hospital Pharmacy Coalition (Washington, DC).

Table 4. Public Hospital Drug Expenditures and FSS Savings

Hospital	Decrease in Hosp. Expend. When Always Using FSS Prices vs. Hosp. Prices (Top 100 Drugs)	Decrease in Hosp. Expend. When Using Lowest Price (Hosp. or FSS) vs. Hosp. Price (Top 100 Drugs)	FSS Price as Mean % Decrease from Hospital Price (Simple mean) (unweighted) (Top 100 Drugs)	Drug Expend. Savings Only from Drugs with FSS Price < Hosp. Price (Top 100 Drugs)	% of Current Drug Expenditures Which Have an FSS Price < Hosp. Price (Top 100 Drugs)
A	15.9%	21.7%	16.6%	25.7%	84.5%
B	18.5%	21.2%	19.9%	24.1%	88.0%
C	15.2%	19.5%	15.4%	22.3%	87.3%
D	15.9%	24.4%	19.1%	27.5%	88.7%
E	18.3%	20.9%	22.1%	26.5%	78.9%
F	14.6%	18.5%	17.7%	22.2%	83.1%
G	23.9%	26.9%	23.3%	30.1%	89.2%
H	20.2%	21.3%	22.2%	24.0%	88.8%
I	16.4%	18.8%	18.1%	24.0%	78.2%
All Hosp.	17.8%	20.9%	18.9%	25.1%	83.3%

Hospital	Hospital Drug Expenditure: When Using Current Hospital Price (Top 100 Drugs)	Hospital Drug Expenditure: When Always Using FSS Price (Top 100 Drugs)	Hospital Drug Expenditure: When Using Lowest Price (FSS or Hospital) (Top 100 Drugs)	Hospital Drug Expenditure @ Hospital Prices: Only for Drugs with FSS Price < Hospital Price (Top 100 Drugs)	Hospital Drug Expenditure @ FSS Prices: Only for Drugs with FSS Price < Hospital Price (Top 100 Drugs)
A	$ 3,946,444.75	$ 3,319,291.66	$ 3,091,285.07	$ 3,333,742.82	$ 2,478,583.14
B	$ 5,073,628.28	$ 4,134,291.95	$ 3,997,363.59	$ 4,465,661.85	$ 3,389,397.16
C	$ 4,154,425.34	$ 3,521,557.67	$ 3,343,899.82	$ 3,627,219.97	$ 2,816,694.45
D	$ 456,699.72	$ 384,237.83	$ 345,107.74	$ 405,130.64	$ 293,538.66
E	$ 9,247,665.91	$ 7,551,929.19	$ 7,312,444.41	$ 7,296,046.62	$ 5,360,825.12
F	$ 1,603,953.01	$ 1,369,825.28	$ 1,307,529.56	$ 1,332,297.74	$ 1,035,874.29
G	$ 2,924,917.08	$ 2,226,987.69	$ 2,138,600.66	$ 2,609,276.18	$ 1,822,959.76
H	$ 2,895,787.13	$ 2,311,261.56	$ 2,277,730.88	$ 2,570,624.74	$ 1,952,568.49
I	$ 7,663,353.48	$ 6,405,700.33	$ 6,224,584.24	$ 5,992,029.38	$ 4,553,260.14
All Hosp.	$ 37,966,874.70	$ 31,225,083.16	$ 30,038,545.97	$ 31,632,029.94	$ 23,703,701.21

SOURCE: Data collected in a survey conducted by the Public Hospital Pharmacy Coalition (Washington, DC) in October 1996.

KEY CONTACTS ON COOPERATIVE PURCHASING ISSUE

Please call today to express your opposition of the repeal of Section 1555 of the Federal Acquisition Streamlining Act (FASA).

	Position	Staffer	Phone/Fax
Sen. Fred Thompson (R-TN)	Chairman Senate Gov. Affairs Comm.	Ellen Brown	224-4751 228-3679
Sen. John Glenn (D-OH)	Ranking Minority Member, SGA Comm.	Brian Dettlebech	224-2623 224-7983
Sen. Ted Stevens (R-AK)	Chairman Senate Approp. Comm.	Steve Cortese	224-3471 224-2354
Sen. Robert Byrd (D-WV)	Ranking Minority Member	James English	224-7200 224-8070
Rep. Dan Burton (R-IN)	Chairman House Gov. Reform & Oversight Comm.	Bill O'Neil	225-5074 225-0016
Rep. Steve Horn (R-CA)	Chairman Gov. Management Information & Technology Comm.	Mark Brasher	225-5147 226-1012
Rep. Bob Livingston (R-LA)	Chairman House Approp. Comm.	Jim Dwyer	225-2771 225-0739
Rep. Jim Kolbe (R-AZ)	Chairman Treasury, Postal Service and General Government Approp. Subcomm.	Betsy Phillips	225-5843 225-0398

31960429.W51

340B Program Contract Price Savings for AIDS Drugs

	340B Program Contract Price	Avg. Wholesale Price	Savings	Savings %
ANTIVIRALS				
AZT (retrovir) -- Glaxo				
100 mg. caps	$107.20	$159.00*	$51.80	33%
DDI (videx) -- B-M Squibb				
25 mg. tabs	$15.35			
50 mg. tabs	$30.69			
100 mg. tabs	$61.36	$115.00*	$53.54	47%
150 mg. tabs	$92.08			
D4T				
40 mg.	$155.00	$249.00*	$94.00	38%
Saquinovir				
200 mg.	$401.00	$606.00*	$205.00	33%
CMV				
Foscarnet (foscavir) -- Astra				
250 ml.	$585.00	$879.30	$294.30	33%
500 ml.	$1,165.02	$1,751.10	$586.08	33%
Cytovene (ganciclovir) -- Roche				
250 mg. caps	$486.16	$702.00	$215.84	31%
500 mg. inj.	$602.50	$870.00	$267.50	31%
HERPES				
Famvir -- S-K Beecham				
500 mg. tabs	$122.94	$184.50	$61.56	33%
500 mg. s.u.p.	$207.89	$340.07	$132.18	39%
Zovirax (acyclovir) -- Burr. Wellcome				
200 mg. caps	$51.19	$97.63	$46.44	48%
500 mg. powder	$323.77	$509.04	$185.27	36%
800 mg. tabs	$233.60	$375.79	$142.19	38%

* Retail Price

340B Program Contract Price Savings for AIDS Drugs

	340B Program Contract Price	Avg. Wholesale Price	Savings	Savings %
KAPOSI'S SARCOMA				
Interferon (alfa) -- Roche				
36 mm.	$181.00	$358.38	$177.38	49%
9 mm.	$53.47	$84.14	$30.67	36%
3 mm.	$15.54	$29.87	$14.33	48%
PNEUMONIA				
Pentamidine -- Abbott				
300 mg.	$53.48	$109.17	$55.69	51%
TB				
Rifabutin (mycobutin) -- Pharmacia				
150 mg.	$253.20	$341.00	$87.80	26%
WASTING				
Marinol (dronainol) -- Roxanne				
10 mg. caps	$117.50	$309.40	$191.90	62%
2.5 mg. caps	$118.00	$268.50	$150.50	56%
5 mg. caps	$238.00	$528.00	$290.00	55%
Megace -- B-M Squibb				
20 mg. tabs	$26.26	$69.96	$43.70	62%
40 mg. tabs	$61.93	$124.79	$62.86	50%

31770596

* Retail Price

From: Dennis Styrsky MDG Associates Fax: (708) 839-6626 Voice: (708) 839-6626 To: Ted Slafsky at: public Health Pharmacy Coalition

AIDS Drug Pricing Matrix

11-May-97

Brand Name	Generic Description	Pkg Qty/Size	Manufacturer	FSS Price	AWP Price	Difference	% Savings
CRIXIVAN							
	INDINAVIR SULFATE 200MG CAP	270UU	MERCK & CO	$201.15	$337.50	$136.35	40.40%
	INDINAVIR SULFATE 200MG CAP	360UU	MERCK & CO	$268.20	$450.00	$181.80	40.40%
	INDINAVIR SULFATE 400MG CAP	180UU	MERCK & CO	$268.20	$451.00	$182.80	40.53%
CYTOVENE							
	GANCICLOVIR 500MG/VIL INJ	1X25VIA	ROCHE LABS	$724.98	$870.00	$145.02	16.67%
	GANCICLOVIR 250MG CAP	180	ROCHE LABS	$584.99	$702.00	$117.01	16.67%
EPIVIR							
	LAMIVUDINE 150MG TAB	60	GLAXO INC	$192.97	$230.41	$37.44	16.25%
	LAMIVUDINE 10MG/ML SOLN,ORAL	240ML	GLAXO INC	$51.46	$61.44	$9.98	16.24%
FAMVIR							
	FAMCICLOVIR 500MG S.U.P. TAB	50	SKB/PENN LAB	$201.49	$340.07	$138.58	40.75%
	FAMCICLOVIR 500MG TAB	30	SKB/PENN LAB	$87.12	$184.50	$97.38	52.78%

(1) Not currently available on FSS as of May 8,1997. May be in negotiation or not yet published.

AWP Prices are taken from the 1997 copy of the "Drug Topics Redbook"

1

Brand Name	Generic Description	Pkg Qty/Size	Manufacturer	FSS Price	AWP Price	Difference	% Savings
FOSCAVIR							
	FOSCARNET NA 24MG/ML INJ,IV	12X250M	ASTRA PHARM	$525.84	$879.30	$353 46	40.20%
	FOSCARNET NA 24MG/ML INJ,IV	12X500M	ASTRA PHARM	$1,057.50	$1,751.10	$693 60	39.61%
INVIRASE							
	SAQUINAVIR 200MG CAP	270	ROCHE LABS	$476.70	$572.06	$95.36	16.67%
MEGACE							
	MEGESTROL ACETATE 20MG TAB	100	BRISTOL LAB	$21.11	$75.86	$54.75	72.17%
	MEGESTROL ACETATE 40MG TAB	100	BRISTOL LAB	$42.21	$134.96	$92 75	68 72%
MYCOBUTIN							
	RIFABUTIN 150MG CAP	1	UPJOHN/PHARM	$299.16	$393.08	$93.92	23.89%
PENTAMIDINE							
	PENTAMIDINE ISETHIONATE 300MG/VIL INJ	25X300M	ABBOTT LAB	$39.06	$119.21	$80.15	67.23%
RETROVIR							
	ZIDOVUDINE 100MG CAP	100	GLAXO INC	$133.40	$159.29	$25.89	16.25%
ROFERON-A							
	INTERFERON ALFA-2A,RECOMBINANT 9 MILLION UNT/0.9ML VIAL	0.9ML VI	ROCHE LABS	$57.86	$92.76	$34.90	37.62%

(1) Not currently available on FSS as of May 8,1997. May be in negotiation or not yet published.

AWP Prices are taken from the 1997 copy of the "Drug Topics Redbook"

Brand Name	Generic Description	Pkg Qty/Size	Manufacturer	FSS Price	AWP Price	Difference	% Savings
ROFERON-A (1)							
	INTERFERON ALFA-2A,RECOMBINANT 3 MILLION UNT/ML VIAL INJ	1ML	ROCHE LABS		$32.94		
	INTERFERON ALFA-2A,RECOMBINANT 36 MILLION UNT/VIAL INJ	1	ROCHE LABS		$395.15		
VIDEX (1)							
	DIDANOSINE 150MG TAB	60	BRISTOL LABS		$139.51		
	DIDANOSINE 25MG TAB	60	BRISTOL LABS		$23.26		
	DIDANOSINE 100MG TAB	60	BRISTOL LABS		$93.01		
	DIDANOSINE 50MG TAB	60	BRISTOL LABS		$46.51		
ZOVIRAX							
	ACYCLOVIR 200MG CAP	100	NOVOPHARM	$31.32	$108.56	$77.24	71.15%
	ACYCLOVIR 800MG TAB	100	NOVOPHARM	$118.44	$409.67	$291.23	71.09%
ZOVIRAX (1)							
	ACYCLOVIR 500MG INJ	10	NOVOPHARM		$566.03		

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AWP Prices are taken from the 1997 copy of the "Drug Topics Redbook"

[DRAFT LETTER OPPOSING REPEAL OF COOPERATIVE PURCHASING PROGRAM]

Dear _____:

As an organization concerned about the affordability and accessibility of pharmaceuticals for HIV-infected persons, we are writing to ask your immediate assistance in opposing Section 323 of the Senate supplemental appropriations bill (S. 672). Section 323 would repeal the federal cooperative purchasing program established under Section 1555 of the Federal Acquisition Streamlining Act of 1994 (FASA).

We understand that, according to a recent study by the Prime Institute at the University of Minnesota, implementation of the federal cooperative purchasing program for pharmaceuticals could lower the cost of drugs, including those used to treat HIV, for public hospitals and state and local health departments by 25 percent or more. In light of the significant budget shortfalls of most state AIDS drug assistance programs and other government-financed HIV programs (including Medicaid), repeal of the cooperative purchasing program would harm both patients and taxpayers.

We also understand that both the General Accounting Office (GAO) and the General Services Administration (GSA) are currently studying the potential impact of cooperative purchasing as directed by Congress early last year. Because neither GAO nor GSA have completed their studies, the Congressional committees with jurisdiction over this program have not had an opportunity to hold hearings and receive comments from affected parties on all sides of this issue. Besides violating the constraint against legislating on an appropriations bill, Section 323 would effectively deny organizations, such as ours, any voice in the debate over the fate of this program.

For these reasons, we strongly urge you to oppose the inclusion of S. 323 in the supplemental appropriations bill.

Sincerely,

21452875.W51

Section 1555 of the Federal Acquisition Streamlining Act: Impact of Cooperative Purchasing on the Pharmaceutical Market

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Acknowledgment: Financial support for this study was provided by the Public Hospital Pharmacy Coalition (Washington, DC).

Table 4. Public Hospital Drug Expenditures and FSS Savings

Hospital	Decrease in Hosp. Expend. When Always Using FSS Prices vs. Hosp. Prices (Top 100 Drugs)	Decrease in Hosp. Expend. When Using Lowest Price (Hosp. or FSS) vs. Hosp. Price (Top 100 Drugs)	FSS Price as Mean % Decrease from Hospital Price (Simple mean) (unweighted) (Top 100 Drugs)	Drug Expend. Savings Only from Drugs with FSS Price < Hosp. Price (Top 100 Drugs)	% of Current Drug Expenditures Which Have an FSS Price < Hosp. Price (Top 100 Drugs)
A	15.9%	21.7%	16.6%	25.7%	84.5%
B	18.5%	21.2%	19.9%	24.1%	88.0%
C	15.2%	19.5%	15.4%	22.3%	87.3%
D	15.9%	24.4%	19.1%	27.5%	88.7%
E	18.3%	20.9%	22.1%	26.5%	78.9%
F	14.6%	18.5%	17.7%	22.2%	83.1%
G	23.9%	26.9%	23.3%	30.1%	89.2%
H	20.2%	21.3%	22.2%	24.0%	88.8%
I	16.4%	18.8%	18.1%	24.0%	78.2%
All Hosp.	17.8%	20.9%	18.9%	25.1%	83.3%

Hospital	Hospital Drug Expenditure: When Using Current Hospital Price (Top 100 Drugs)	Hospital Drug Expenditure: When Always Using FSS Price (Top 100 Drugs)	Hospital Drug Expenditure: When Using Lowest Price (FSS or Hospital) (Top 100 Drugs)	Hospital Drug Expenditure @ Hospital Prices: Only for Drugs with FSS Price < Hospital Price (Top 100 Drugs)	Hospital Drug Expenditure @ FSS Prices: Only for Drugs with FSS Price < Hospital Price (Top 100 Drugs)
A	$ 3,946,444.75	$ 3,319,291.66	$ 3,091,285.07	$ 3,333,742.82	$ 2,478,583.14
B	$ 5,073,628.28	$ 4,134,291.95	$ 3,997,363.59	$ 4,465,661.85	$ 3,389,397.16
C	$ 4,154,425.34	$ 3,521,557.67	$ 3,343,899.82	$ 3,627,219.97	$ 2,816,694.45
D	$ 456,699.72	$ 384,237.83	$ 345,107.74	$ 405,130.64	$ 293,538.66
E	$ 9,247,665.91	$ 7,551,929.19	$ 7,312,444.41	$ 7,296,046.62	$ 5,360,825.12
F	$ 1,603,953.01	$ 1,369,825.28	$ 1,307,529.56	$ 1,332,297.74	$ 1,035,874.29
G	$ 2,924,917.08	$ 2,226,987.69	$ 2,138,600.66	$ 2,609,276.18	$ 1,822,959.76
H	$ 2,895,787.13	$ 2,311,261.56	$ 2,277,730.88	$ 2,570,624.74	$ 1,952,568.49
I	$ 7,663,353.48	$ 6,405,700.33	$ 6,224,584.24	$ 5,992,029.38	$ 4,553,260.14
All Hosp.	$ 37,966,874.70	$ 31,225,083.16	$ 30,038,545.97	$ 31,632,029.94	$ 23,703,701.21

SOURCE: Data collected in a survey conducted by the Public Hospital Pharmacy Coalition (Washington, DC) in October 1996

KEY CONTACTS ON COOPERATIVE PURCHASING ISSUE

Please call today to express your opposition of the repeal of Section 1555 of the Federal Acquisition Streamlining Act (FASA).

	Position	Staffer	Phone/Fax
Sen. Fred Thompson (R-TN)	Chairman Senate Gov. Affairs Comm.	Ellen Brown	224-4751 228-3679
Sen. John Glenn (D-OH)	Ranking Minority Member, SGA Comm.	Brian Dettlebech	224-2623 224-7983
Sen. Ted Stevens (R-AK)	Chairman Senate Approp. Comm.	Steve Cortese	224-3471 224-2354
Sen. Robert Byrd (D-WV)	Ranking Minority Member	James English	224-7200 224-8070
Rep. Dan Burton (R-IN)	Chairman House Gov. Reform & Oversight Comm.	Bill O'Neil	225-5074 225-0016
Rep. Steve Horn (R-CA)	Chairman Gov. Management Information & Technology Comm.	Mark Brasher	225-5147 226-1012
Rep. Bob Livingston (R-LA)	Chairman House Approp. Comm.	Jim Dwyer	225-2771 225-0739
Rep. Jim Kolbe (R-AZ)	Chairman Treasury, Postal Service and General Government Approp. Subcomm.	Betsy Phillips	225-5843 225-0398

340B Program Contract Price Savings for AIDS Drugs

	340B Program Contract Price	Avg. Wholesale Price	Savings	Savings %
ANTIVIRALS				
AZT (retrovir) -- Glaxo				
100 mg. caps	$107.20	$159.00*	$51.80	33%
DDI (videx) -- B-M Squibb				
25 mg. tabs	$15.35			
50 mg. tabs	$30.69			
100 mg. tabs	$61.36	$115.00*	$53.54	47%
150 mg. tabs	$92.08			
D4T				
40 mg.	$155.00	$249.00*	$94.00	38%
Saquinovir				
200 mg.	$401.00	$606.00*	$205.00	33%
CMV				
Foscarnet (foscavir) -- Astra				
250 ml.	$585.00	$879.30	$294.30	33%
500 ml.	$1,165.02	$1,751.10	$586.08	33%
Cytovene (ganciclovir) -- Roche				
250 mg. caps	$486.16	$702.00	$215.84	31%
500 mg. inj.	$602.50	$870.00	$267.50	31%
HERPES				
Famvir -- S-K Beecham				
500 mg. tabs	$122.94	$184.50	$61.56	33%
500 mg. s.u.p.	$207.89	$340.07	$132.18	39%
Zovirax (acyclovir) -- Burr. Wellcome				
200 mg. caps	$51.19	$97.63	$46.44	48%
500 mg. powder	$323.77	$509.04	$185.27	36%
800 mg. tabs	$233.60	$375.79	$142.19	38%

* Retail Price

340B Program Contract Price Savings for AIDS Drugs

	340B Program Contract Price	Avg. Wholesale Price	Savings	Savings %
KAPOSI'S SARCOMA				
Interferon (alfa) -- Roche				
36 mm.	$181.00	$358.38	$177.38	49%
9 mm.	$53.47	$84.14	$30.67	36%
3 mm.	$15.54	$29.87	$14.33	48%
PNEUMONIA				
Pentamidine -- Abbott				
300 mg.	$53.48	$109.17	$55.69	51%
TB				
Rifabutin (mycobutin) -- Pharmacia				
150 mg.	$253.20	$341.00	$87.80	26%
WASTING				
Marinol (dronainol) -- Roxanne				
10 mg. caps	$117.50	$309.40	$191.90	62%
2.5 mg. caps	$118.00	$268.50	$150.50	56%
5 mg. caps	$238.00	$528.00	$290.00	55%
Megace -- B-M Squibb				
20 mg. tabs	$26.26	$69.96	$43.70	62%
40 mg. tabs	$61.93	$124.79	$62.86	50%

31770596

* Retail Price

From: Dennis Styrsky MDG Associates Fax: (708) 839-5626 Voice: (708) 839-5626 To: Ted Siatsky at: public Health Pharmacy Coalition

AIDS Drug Pricing Matrix

11-May-97

Brand Name	Generic Description	Pkg Qty/Size	Manufacturer	FSS Price	AWP Price	Difference	% Savings
CRIXIVAN							
	INDINAVIR SULFATE 200MG CAP	270UU	MERCK & CO	$201.15	$337.50	$136 35	40.40%
	INDINAVIR SULFATE 200MG CAP	360UU	MERCK & CO	$268.20	$450.00	$181 80	40.40%
	INDINAVIR SULFATE 400MG CAP	180UU	MERCK & CO	$268.20	$451.00	$182.80	40.53%
CYTOVENE							
	GANCICLOVIR 500MG/VIL INJ	1X25VIA	ROCHE LABS	$724 98	$870.00	$145 02	16.67%
	GANCICLOVIR 250MG CAP	180	ROCHE LABS	$584.99	$702.00	$117.01	16 67%
EPIVIR							
	LAMIVUDINE 150MG TAB	60	GLAXO INC	$192.97	$230.41	$37.44	16.25%
	LAMIVUDINE 10MG/ML SOLN,ORAL	240ML	GLAXO INC	$51.46	$61.44	$9.98	16.24%
FAMVIR							
	FAMCICLOVIR 500MG S U.P. TAB	50	SKB/PENN LAB	$201.49	$340.07	$138 58	40.75%
	FAMCICLOVIR 500MG TAB	30	SKB/PENN LAB	$87.12	$184.50	$97.38	52.78%

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AWP Prices are taken from the 1997 copy of the "Drug Topics Redbook"

From: Dennis Styrsky MDG Associates Fax: (708) 839-6626 Voice: (708) 839-6626 To: Ted Slafsky at public Health Pharmacy Coalition

Brand Name	Generic Description	Pkg Qty/Size	Manufacturer	FSS Price	AWP Price	Difference	% Savings
FOSCAVIR							
	FOSCARNET NA 24MG/ML INJ,IV	12X250M	ASTRA PHARM	$525.84	$879.30	$353 46	40 20%
	FOSCARNET NA 24MG/ML INJ,IV	12X500M	ASTRA PHARM	$1,057.50	$1,751.10	$693 60	39 61%
INVIRASE							
	SAQUINAVIR 200MG CAP	270	ROCHE LABS	$476.70	$572.06	$95.36	16.67%
MEGACE							
	MEGESTROL ACETATE 20MG TAB	100	BRISTOL LAB	$21.11	$75.86	$54.75	72.17%
	MEGESTROL ACETATE 40MG TAB	100	BRISTOL LAB	$42.21	$134.96	$92.75	68 72%
MYCOBUTIN							
	RIFABUTIN 150MG CAP	1	UPJOHN/PHARM	$299.16	$393.08	$93.92	23.89%
PENTAMIDINE							
	PENTAMIDINE ISETHIONATE 300MG/VIL INJ	25X300M	ABBOTT LAB	$39.06	$119.21	$80.15	67.23%
RETROVIR							
	ZIDOVUDINE 100MG CAP	100	GLAXO INC	$133.40	$159.29	$25 89	16.25%
ROFERON-A							
	INTERFERON ALFA-2A,RECOMBINANT 9 MILLION UNT/0.9ML VIAL	0.9ML VI	ROCHE LABS	$57.86	$92.76	$34.90	37.62%

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Brand Name	Generic Description	Pkg Qty/Size	Manufacturer	FSS Price	AWP Price	Difference	% Savings
ROFERON-A (1)							
	INTERFERON ALFA-2A,RECOMBINANT 3 MILLION UNT/ML VIAL INJ	1ML	ROCHE LABS		$32.94		
	INTERFERON ALFA-2A,RECOMBINANT 36 MILLION UNT/VIAL INJ	1	ROCHE LABS		$395.15		
VIDEX (1)							
	DIDANOSINE 150MG TAB	60	BRISTOL LABS		$139.51		
	DIDANOSINE 25MG TAB	60	BRISTOL LABS		$23.26		
	DIDANOSINE 100MG TAB	60	BRISTOL LABS		$93.01		
	DIDANOSINE 50MG TAB	60	BRISTOL LABS		$46.51		
ZOVIRAX							
	ACYCLOVIR 200MG CAP	100	NOVOPHARM	$31.32	$108.56	$77.24	71.15%
	ACYCLOVIR 800MG TAB	100	NOVOPHARM	$118.44	$409.67	$291.23	71.09%
ZOVIRAX (1)							
	ACYCLOVIR 500MG INJ	10	NOVOPHARM		$566.03		

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