

HIV Treatment & Care From Approval to Access

Since the beginning of the AIDS epidemic, the response in the United States to this devastating crisis has been primarily emotional and often cruel – denial, disgust, neglect, fear, and blame. Only rarely has our country addressed the epidemic as the true healthcare crisis that it is. Like the rest of our healthcare system, benefits and medical services for most people with HIV come from a variety of fractured and piecemeal sources, often with cumbersome eligibility requirements. This issue of *ACRIA Update* includes articles by respected advocates about these sources for services, medical care, and treatment. The content of these articles was primarily driven by questions people with HIV ask during ACRIA’s treatment education workshops.

In the last year, there has been a fair amount of media coverage about the approximately 1,600 people on waiting lists for the AIDS Drug

Assistance Programs (ADAPs) in various states. What isn’t widely discussed is that the non-prof- it Institute of Medicine released a report last May estimating that nearly 59,000 people with HIV in the United States currently need antiretroviral treatment but have no access to it. In part, this is due to the fact that many people can’t even get on an ADAP waiting list since the income require- ments are so low in many states.

The goal of this issue of *ACRIA Update* isn’t only to provide information. Access to health- care for most people with HIV is more precari- ous now than ever. We hope that the resources included in the issue and the actions suggested by the writers will inspire more people to advocate for a comprehensive system of healthcare in the United States that not only serves the needs of people with HIV but everyone in need of care.

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The Food and Drug Administration The Process of Approval

by *Tim Horn*

For every dollar the typical American spends, approximately 25 cents goes to products that are regulated by the U.S. Food and Drug Administration (FDA). We’re talking about everything from food, to drugs, to radiation-emitting products like cell phones, to cosmetics. With respect to drugs used for medical conditions, the regulatory role of the FDA reflects the sometimes paradoxical needs of consumers: facilitating rapid access to new therapeutics that show promise for patients, while also protecting them from products that are ineffective, unsafe, and marketed using unproven claims.

When it comes to the approval and regulation of drugs used to treat HIV and AIDS, the role of the FDA and its various regulations can be

extremely complex. Confusing matters further, the role of the FDA is continually being shifted and reshaped in accordance with new, some- times conflicting laws designed to protect con- sumers and the pharmaceutical industry. In fact, many FDA regulations in place today – such as expanded access and accelerated approval of promising drugs for life-threatening conditions – arose in response to the HIV/AIDS epidemic.

In order to highlight the most important infor- mation about the Byzantine activities of the FDA as they relate to HIV and AIDS drugs, *ACRIA Update* asked ACRIA’s treatment edu- cation team and Community Advisory Board to come up with a list of frequently asked ques- tions about the FDA and its activities.

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ACRIA is an independent, non-profit, community-based AIDS medical research and treatment education organization dedicated to rapidly improving the length and quality of life for people living with HIV/AIDS. Bulk copies of *ACRIA Update* are available free to agencies that provide services to people living with HIV/AIDS. For more information, call 212-924-3934 ext. 120.

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Tipranavir Open Label Safety Study

People whose virus has become resistant to approved HIV treatments or who are intolerant to them will take tipranavir with Norvir, along with other anti-HIV drugs, for an open period of time. Participants should be 13 years of age or older, have a viral load above 10,000 and a CD4 count below 100 to enroll in this program.

UK-427,857 for Drug-Resistant HIV

People who have taken anti-HIV drugs from three of the four classes of drugs will take either UK-427 (an experimental HIV attachment inhibitor) with an optimized regimen of anti-HIV drugs, or take a placebo (dummy pill) with the optimized regimen, for 11 months. Participants must be 16 or older and have a viral load of at least 5,000.

The Effect of Reyataz on Cholesterol Levels

People who have high cholesterol levels and a viral load below 50 while taking Kaletra will either switch to Reyataz or continue taking Kaletra. The study will last 12 months. Study participants will be reimbursed \$25 for each visit.

Reyataz Compared to Kaletra

People whose viral load has risen to over 1,000 while taking an NNRTI as part of their first HAART regimen will switch to either Kaletra, or to Reyataz / Norvir. Everyone will also take Viread and either Videx EC or Zerit XR. The study will last for 22 months. Study participants will be reimbursed \$25 for each visit.

One-day study of Reyataz Resistance

People whose viral load has risen to over 1,000 while taking Reyataz will have blood tests for resistance, CD4 and viral load. Study participants will be reimbursed \$25.

Phase I Study of a New GlaxoSmithKline NNRTI

People who have become resistant to an NNRTI and who have a CD4 count over 200 and a viral load over 2,000 will take one of four doses of W695634G alone, or take placebo pills, for 7 days. Those who complete the study will be reimbursed \$590.

For the above trials, contact Dr. Douglas Mendez at 212-924-3934 ext. 126 or Dr. Yuriy Akulov at ext. 124.

Standard of Care Treatment vs. ZEST Once-Daily Regimen

(Closed to Enrollment) This trial is studying whether people on their first HAART regimen who take their drugs two or more times a day can switch to a once-daily regimen. People in the trial either remain on their current medications, or switch to Zerit XR, Epivir and Sustiva (ZEST) taken once daily.

Editor's Notes

- All material in *ACRIA Update* is presented for educational and informational purposes only, and is not intended as medical advice. All decisions regarding one's personal treatment and therapy choices should be made in consultation with a physician.
- *ACRIA Update* refers to most drugs by both their commercial and scientific names upon their first reference in an article. Thereafter in the article, they will be identified with the name by which we feel they are most commonly known, either commercial or scientific.

Food and Drug Administration *(continued from page 1)*

Who decides whether the FDA approves a drug?

Once clinical trials have been completed, the approval process begins with a pharmaceutical company filing a New Drug Application (NDA) with the FDA's Center for Drug Evaluation and Research (CDER). The NDA contains volumes of paper describing everything that has been learned about the drug, including data from test tube studies, animal studies, initial dosing studies in HIV-negative and HIV-positive people, along with the results of all safety and effectiveness studies that have been completed to-date.

If CDER finds the NDA to be in order – meaning that it contains complete and sufficient information to review – the FDA usually passes the NDA on to an advisory committee made up of non-FDA experts. When it comes to antiretroviral agents, it is the Antiviral Drugs Advisory Committee (ADAC) that reviews the NDA. ADAC is made up of researchers and clinicians with significant experience in the field of HIV research and care. At least one community representative – usually a knowledgeable treatment activist/educator working for an AIDS service organization – also serves as a voting member of ADAC.

In reviewing the NDA, ADAC often holds a public meeting with the pharmaceutical company and members of the FDA to hear oral arguments in support of – and sometimes against – the drug's approval. At the close of the meeting, the ADAC members take a vote, deciding whether or not to recommend approval of the drug. If ADAC votes to recommend approval, the FDA usually grants it – in the form of a letter sent to the pharmaceutical company – typically within days or weeks of the ADAC committee meeting.

Why does one drug get approved and not another?

For much of its early history, the FDA was primarily concerned with one thing when deciding whether or not to approve an investigational drug: safety. In 1962, Congress drafted and passed the

Kefauver-Harris Drug Amendments to the Food, Drug, and Cosmetic Acts in response to the horrifying birth defects caused by thalidomide, a sleeping pill approved at the time in Europe. The FDA strengthened its safety requirements and began requiring companies to prove that their investigational drug was also effective for the disease it was meant to treat.

Almost all of the anti-HIV drugs that have made their way to the FDA for review have been approved. All except one: adefovir dipivoxil. While this drug is now approved for the treatment of chronic

“If it weren't for community support . . . some medications used today to treat HIV-related problems may not have been approved.”

hepatitis B (under the brand name Hepsvera), it was originally studied as a treatment for HIV. At the dose needed to effectively suppress HIV (40 mg a day), clinical trials found that it was associated with a high rate of kidney problems, with 214 patients participating in these studies requiring dialysis. The ADAC reviewing the NDA for adefovir dipivoxil also felt that there was “insufficient proof of the drug's effectiveness.”

Essentially, the heart of all FDA activities is a judgment about whether a product's benefits to users will outweigh its risks. In the case of adefovir, the risks appeared to outweigh the benefits. Given the high cost of developing a new drug, pharmaceutical companies are usually quick to pull the

plug on an investigational candidate before an NDA is filed if the drug appears to be ineffective or too toxic in early clinical trials.

A little pressure from community activists can go a long way as well. There have been instances in which the FDA has been provided with an NDA containing limited convincing data. If it weren't for community support for the drug – including public testimony from patients who benefited from the drug in clinical trials – some medications used today to treat HIV-related problems may not have been approved.

How long does it take for a drug to become available after the FDA approves it?

Even before the FDA officially reviews an NDA, the sponsoring pharmaceutical company is usually hard at work producing mass quantities of a drug in anticipation of approval. This is, undoubtedly, a risky business decision – beginning production of a drug, along with the costly development of advertising and sales materials, before the FDA has given the company an official green light.

Fortunately, this decision usually pays off and HIV-positive people in need of the drug can sometimes look forward to its widespread availability within just days of approval. Post-approval access isn't always this easy, however. Sometimes it can take several weeks or months for a pharmaceutical company to have enough drug available for widespread distribution after its approval.

This is what happened with Crixivan (indinavir), Merck's protease inhibitor, when it was approved in 1996, resulting in limited distribution through a single mail-order pharmacy. This was also the case with Fuzeon (enfuvirtide), Hoffmann-La Roche's entry inhibitor. Given the complexities and time-consuming process associated with the manufacturing of this drug, the company predicted that it would only have enough drug supply for 15,000 people worldwide during the first several months after approval.

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Initially, this created anxiety and panic among AIDS activists working to secure Fuzeon access for everyone who needed it. But in reality, the limited demand for Fuzeon – because of its cumbersome injectable dosing and its high cost – ended up being more of a problem than the limited supply of the drug.

How much safety can a clinical trial for an experimental drug assure?

Generally speaking, most experimental anti-HIV drugs reviewed by the FDA today have been tested in at least one study that was conducted for at least 48 weeks (approximately one year). When a drug is first approved, it is reasonable to say that we know a lot about its short-term complications: toxicities and side effects that may arise during the first year of treatment.

Many people rightfully argue that this is too limited of a snapshot given that some long-term side effects may occur after several months or years of continued use. Unfortunately, this has been the case with a number of anti-HIV drugs. For example, long after they were approved for use, we learned that nucleoside analogues such as Zerit and Videx – if used for long periods of time – can cause damage to mitochondria, the tiny powerhouses inside cells. Similarly, we learned that long-term protease inhibitor use is associated with increases in cholesterol, triglycerides, and glucose levels, along with abnormal body-shape changes. Because the clinical trials needed to approve these drugs were only 24 to 48 weeks in duration, these long-term side effects weren't documented until after the drugs were approved.

Some pharmaceutical companies collect long-term follow-up data from studies that continue well after the drug is approved, allowing for continual updates of a drug's package insert to document both short- and long-term side effects. All package inserts, including revisions, are reviewed by the FDA before they can be distributed. Package inserts are the accor-

dion-folded pieces of paper that accompany packaged medications reviewing their effectiveness, safety, and dosing requirements.

What is Expanded Access?

Compassionate Use?

Treatment IND? Parallel Track?

These are all programs that helped set the stage for accelerated approval. They are still used today to help make promising experimental treatments available to people with life-threatening diseases who aren't benefiting from approved treatments and don't qualify for clinical trials. **Expanded access** is the general term for any program that allows doctors and their patients to gain access to medications outside of controlled clinical trials before the FDA officially approves them.

Prior to the activism surrounding HIV/AIDS drug development, expanded access usually came in the form of **compassionate** use allowances, which were often quite cumbersome. First, a doctor had to get permission from a company to use its experimental agent in a desperately ill patient (lots of paperwork). If permission was granted, the doctor then had to request authorization from the FDA to use the drug in his or her patient (even more paperwork). This process sometimes took weeks or months.

In response to the activism aroused by the limited availability of Retrovir (AZT) when it was being developed, the FDA created **treatment investigational new drug (treatment IND)** regulations, which went into effect on June 22, 1987. These regulations allowed pharmaceutical companies to set up programs to help doctors and patients gain access to investigational drugs in a much more efficient manner, usually in exchange for regular reports tracking the patients' progress (and problems) while receiving the treatment. Before being allowed to open a treatment IND program, the company had to provide the FDA with data indicating that the drug was both safe and effective. Within months, however, community

activists protested that treatment INDs weren't likely to be useful, given that the safety and effectiveness data requirements were too stringent. This, they argued, only shaved six months off the time that the drug would otherwise be made available through the usual approval process.

Soon, regulations were published announcing a new expanded access approach: **parallel track**. As its name implies, this program would be provided on a track that ran parallel to the needed safety and effectiveness clinical trials of the drug. Parallel track was designed specifically with investigational anti-HIV drugs in mind. It made investigational drugs available much earlier in the development process, after reasonable safety – but not necessarily effectiveness – had been determined in clinical trials. Parallel track programs usually take the form of a large national study (sometimes called an open-label safety study), designed to collect safety data until the drug is approved (and sometimes thereafter), in which any doctor treating needy HIV-positive patients can participate.

While these expanded access programs seemed ideal in terms of rapidly making new treatments available to the sickest HIV-positive people, they were also problematic. One problem was fairness. Because of all the initial and follow-up paperwork involved in expanded access programs, many doctors didn't have the time or resources to enroll patients. Patients who had private health insurance – and were being seen by private medical doctors with flexible schedules and support staff – were most likely to benefit from these programs. HIV-positive patients receiving care through public clinics, where doctors have enormous caseloads and little assistance, were often left out of the process. In turn, the focus shifted away from expanded access programs to initiatives to make new drugs widely available by prescription by speeding up the FDA drug approval process.

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Medicaid and Medicare:

Ripping Holes in the Safety Net

“Of all the forms of inequality, injustice in healthcare is the most shocking and inhumane.” Martin Luther King

Some forty years since these words were spoken, the United States remains the only Western industrialized country that hasn't found a way to provide healthcare to all its citizens. Although government programs like Medicaid and Medicare have done an admirable job of serving vulnerable people, they remain part of a fractured system with many gaps.

Tax cuts benefiting the wealthy, war spending, and a sluggish economy are increasing the national debt while decreasing our ability to pay for health care. At the same time, the cost of care is rising considerably. In 2002, healthcare costs increased by 8.3%, the highest since 1991. These increases, coupled with less available funding for healthcare, have caused cutbacks and restrictions in the programs that people depend on for life prolonging care. (See ADAP article on page 12.)

As of 2003, 45 million Americans were uninsured, with millions more underinsured. Rates of those without health insurance are higher among people of color. In 2002, 14.2 percent of whites were uncovered, while 20.2 percent of African Americans lacked insurance as did 18 percent of Asian and Pacific Islanders and 32.4 percent of Latinos. Most of the uninsured are working, suffering from a long-term trend of fewer employers offering health coverage. Even those who have employer-based insurance are hurt by the trend toward fewer options and less generous plans, leading to burdensome out-of-pocket costs.

Why Should We Worry About Health Care?

Strained systems of care are even more problematic for people with life-threatening illness. People with HIV not only need access to healthcare, but also need to see an HIV specialist in order to maintain overall health and may need other special-

ists for disease complications. Combinations of expensive medications are needed to treat HIV disease as it advances. Without comprehensive, affordable healthcare, including an adequate prescription drug benefit, people with HIV will lose health and eventually face death.

About a third to a half of people with HIV are estimated to be in medical care, and only about a third of those have private insurance. Between 70 and 83 percent either depend on public programs or are uninsured. Half depend on Medicaid and

“Without comprehensive, affordable health care, including prescription drugs, people with HIV will lose health and eventually face death.”

Medicare. It is public programs that are most clearly showing the increasing strain as they suffer cutbacks and restrictions. In order to ensure that we can advocate for these programs, it's important to understand them.

Medicaid and Medicare

Medicaid is the largest public payer of HIV care, serving about 55% of people living with AIDS and 90% of HIV-positive children. Medicare follows second, spending \$2.6 billion in federal funds in 2004, compared to Medicaid's \$5.4 billion. Many people are understandably confused by the difference between the programs and unclear about their coverage. Adding to the confusion, over 50,000 Americans living with AIDS qualify for both.

by Anne Donnelly

Medicaid and Medicare are entitlement programs, meaning that those who qualify must receive covered benefits. However, Medicaid is a joint program run by the federal government and the states, and each state has great flexibility in whom it serves and the benefits it provides. Medicare, on the other hand, is a uniform federal program. For full descriptions of Medicaid and Medicare, visit the Kaiser Family Foundation website at www.kff.org.

Medicaid - Eligibility:

Medicaid is the safety net healthcare program that serves three main groups of low-income Americans: parents and children, the elderly, and the disabled. In order to qualify, people must fall into a specified category. There are over 25 categories falling into five broad groups: children; pregnant women; adults in families with dependent children; people with disabilities; and the elderly.

Most people with HIV enter Medicaid through disability. In general, the state is required to use the disability criteria established for the Supplemental Security Insurance (SSI) program, but can choose to use a more restrictive definition. To qualify, an individual has to have a severe “medically determinable physical or mental impairment” and be unable to engage in any “substantial gainful activity.” These determinations can take a long time and require a lot of paperwork. Even though people with HIV can qualify for presumptive eligibility, meaning they get faster access to benefits, in most states, they have to document one or more of a specified listing of opportunistic infections, cancers, or conditions.

To qualify you must also meet income and asset requirements, which are set by the state and can differ widely state by state and within state by category of beneficiary. Because states set many financial requirements, in good economic times they may choose to invest in health and cover more people. However, when times

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are difficult, states can change eligibility requirements, leaving some without healthcare.

Eligibility is different for immigrants, however. Undocumented immigrants are not eligible. States can cover legal immigrants residing in the country before August 22, 1996 if they meet all the other requirements. Most legal immigrants who entered the U.S. after that date have to wait five years from their date of entry and live in a state that chooses to cover them. In addition, you must be a resident of the state offering the Medicaid coverage.

Medicaid benefits:

The Medicaid benefits package is broad and flexible. Sometimes that works in favor of the beneficiary, allowing benefits tailored to need. Unfortunately, in difficult budget times, states can also cut back on essential benefits. States must provide minimum mandatory benefits, but have broad discretion regarding optional benefits. Although federal law prohibits states from imposing cost sharing (the amount that someone must pay to get service) on some groups of people who are eligible for Medicaid (beneficiaries), they can require it for other groups for specific services. Cost sharing must be “nominal” and is not supposed to create a barrier to care.

Medicaid benefits are divided into two categories: mandatory and optional. There are twelve mandatory service categories and a range of optional categories. For example, physician visits, lab and x-ray, and hospital in-patient are considered mandatory services, while prescription drugs, targeted case management, and personal care services are considered optional services. Notably for people with HIV, prescription drugs fall in the optional category. However, all states cover prescription drugs and some additional optional services.

Each state has the discretion to limit the scope of services, although it must comply with some federal rules regarding benefits. For example, the state can’t discriminate by limiting services based on a particular

diagnosis, type of illness, or condition. People who are eligible for Medicaid are also entitled by federal law to get services that are medically necessary, although what this means can vary state to state.

Medicaid is a comprehensive safety-net healthcare program, and it is also complex and varies widely from state to state. Understanding your state program generally requires help from either an experienced benefits counselor or case manager. One way to begin to understand your state Medicaid and its services for people with HIV is to visit www.atdn.org and click on The Access Project. You will find a synopsis of your state program and contact numbers. You can also call the Project Inform hotline at 1-800-822-7422 for a referral to a benefits counselor in your area.

Medicare Eligibility:

Medicare is a federal health insurance program that covers the elderly and permanently disabled. Most people over 65 are automatically entitled to Part A of Medicare (Hospital Insurance Program) if they or their spouse are eligible for Social Security payments.

Most people with HIV qualify through disability. In order to qualify, you must have worked for a specified period of time, established disability, and completed a two-year waiting period. Generally, if you receive Social Security payments, you are eligible after the two-year waiting period.

There are no income or asset requirements. Medicare serves anyone who is eligible regardless of previous health history.

Medicare Benefits:

Medicare provides broad coverage of basic benefits but doesn’t provide long-term care and currently has no prescription drug coverage. As of 2006, the new Medicare prescription drug benefit will provide some coverage for beneficiaries. Until January 2006, beneficiaries are entitled to a prescription drug card that allows them a discount on some drugs.

Part A provides inpatient hospital services, skilled nursing facility (SNF) benefits, home health visits following a stay in the hospital or SNF, and hospice care. Part B is voluntary and covers physician and outpatient hospital services, annual mammography and other cancer screenings, and services such as laboratory procedures and medical equipment.

Medicare also has a managed care option called Medicare + Choice. Those plans provide both A and B services to beneficiaries.

Unlike Medicaid, Medicare is administered by the federal government, so it doesn’t have the wide variance that Medicaid does. Medicare also offers a higher reimbursement to providers, making it easier for beneficiaries to find providers. However, it also has relatively high cost sharing obligations that can be difficult for beneficiaries.

In addition, the prescription drug card that is currently being offered to beneficiaries is confusing and difficult to use. Many people haven’t taken the option due to lack of knowledge and, for some, the discounts offered don’t represent a significant savings.

Dual Eligibles:

Over 50,000 people living with HIV are eligible for both Medicaid and Medicare (dual eligible). Most dual enrollees are people with very low incomes and substantial health needs. Medicare covers basic health services for this population, but Medicaid is essential because it pays Medicare cost sharing, including the Part B premium, which amounts to over \$700 annually. It also covers services that Medicare doesn’t, including long-term care, vision, dental, and, until 2006, prescription drugs. Once the Medicare prescription drug benefit is implemented in 2006, dual eligibles will lose their Medicaid prescription drug coverage.

Life-Saving Programs Under Attack

The environment for the provision of healthcare has changed dramatically during the Bush Administration. It has always

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USEFUL RESOURCES

THE FOOD AND DRUG ADMINISTRATION

For more detail about the drug approval process, visit the pages on the FDA website listed below. They include graphic flow-charts of various stages of the process:

- www.fda.gov/cder/handbook/ind.htm
Describes the investigational new drug (IND) application process, which occurs before an experimental drug can begin clinical trials in people.
- www.fda.gov/cder/handbook/develop.htm
Describes drug development from test tube, animal, and human studies through the FDA's review of a New Drug Application (NDA).
- www.fda.gov/cder/handbook/nda.htm
Describes the process beginning with the submission of a New Drug Application (NDA) through to the approval (or not) of an experimental drug for marketing.

The FDA offers a number of free email lists at this site: www.fda.gov/emaillist.html. Click on "FDA HIV/AIDS" to subscribe to the list that emails you information about HIV/AIDS-related products and issues, including approvals, label changes, safety warnings, and notices of upcoming public meetings.

MEDICAID and MEDICARE

For detailed descriptions of Medicaid and Medicare, visit the Kaiser Family Foundation at www.kff.org. For state-specific information, go to www.statehealthfacts.org. You might also want to visit the Centers for Medicare and Medicaid Services:

- Medicaid: www.cms.hhs.gov/medicaid
- Medicare: www.cms.hhs.gov/medicare
- Information about individual State Medicaid programs: www.cms.hhs.gov/states/default.asp

For help enrolling in your state's Medicaid program, go to your local AIDS service or other community-based organization. A benefits counselor can be extremely helpful with this process, since it usually requires quite a lot of paperwork. You can also call your State Department of Health to reach the appropriate department that can help you.

For more information on Medicare benefit advocacy, visit the **HIV Medicine Association** website at

www.hivma.org. Go to "Advocacy" at the top of the page and click on "Medicare."

The **HIV Medicare and Medicaid Working Group** is made up of national and regional HIV/AIDS organizations. To participate, email Project Inform's Treatment Action Network at tan@projectinform.org or The Access Project at theaccessproject@aol.com.

THE RYAN WHITE CARE ACT

For detailed information about the CARE Act, visit: hab.hrsa.gov/history.htm.

This U.S. Department of Health and Human Services site has lots of information, including the history, funding, and populations served by the CARE Act over the years.

ADAP

For detailed information about ADAP, visit the National ADAP Monitoring Project at: www.atdn.org/access/adap/index.html.

For help enrolling in your state's ADAP, it might be best to go to your local AIDS service or other community-based organization. There isn't usually a lot of paperwork, but during a time of stress, having someone help you with it can be invaluable. You could also call your State Department of Health to reach the appropriate person or people who can help you. The following websites have information about each state ADAP:

- **AIDS Treatment Data Network – The Access Project** www.atdn.org
Includes comprehensive information about each state's ADAP, including contact information, eligibility criteria, and links.
- **AIDS Treatment Activist Coalition (ATAC) – Save ADAP** www.atac-usa.org/adap.html
Includes PDF files about each state's ADAP that are easy to download and information about how to get involved with Save ADAP, a national coalition of treatment activists, policy advocates, ADAP clients, and service providers to ensure adequate ADAP funding.
- **ACRIA** www.acria.org
As an online addition to this issue of ACRIA Update, our website includes a list of the ADAP contact information for each state.

Personal Perspective: **Waiting for ADAP**

By Henry E. Dendy

I have been HIV-positive for 20 years and, because of a sporadic work history since my diagnosis, I've used the North Carolina AIDS Drug Assistance Program (ADAP) on occasion. I had to use ADAP again two years ago when I went on long-term disability. The nausea and diarrhea were constant, and the dosing schedule wouldn't allow me to work. When I went on long-term disability, my insurance ended. I applied for Medicaid and, for the first time, encountered an ADAP waiting list. I was on that waiting list for three months.

When my doctor prescribed the new medications I needed at the time, I wasn't sure how I was going to obtain them. I didn't have any money or income. My doctor just gave me the prescriptions. That was it from him. The nurses pointed me in the direction of the local AIDS service organization (ASO) to handle the ADAP paperwork and gave me some information about drug company patient assistance programs. So I went to the ASO for help and, after sending my ADAP application to the state agency that administers the program, I was left in limbo.

I'd been prescribed – and needed – Kaletra, Ziagen, Zerit, Viread, Bactrim, Zofran, promethazine, Wellbutrin, and something for high blood pressure. With major depression, constant fatigue and nausea, a CD4 count of about 90, and a viral load of 75,000, my health was somewhere between fair and not so good. I was somewhat lucky – the wait didn't make my HIV any worse, although it made me even more depressed.

ADAP and Medicaid in North Carolina – and other states – are two different programs, and you're encouraged to apply for both at the same time. The criteria are usually similar for both, but not the same. In a lot of cases, you're denied Medicaid and continue to wait for ADAP to come through.

This is when my persistence came in to play. I went back to the clinic where I was treated and asked what to do until I was approved for the meds through ADAP. I figured out the system mostly by myself. I went to the pharmacies at the clinics when I didn't feel like going, stood in line, and asked a lot of questions. Of course, the main question was – What am I going to do?

At this stage, I had to rely on the drug company patient assistance program for each medication. I had to fill out a trail of paperwork for each one until ADAP or Medicaid became available. I also had to go through a similar process

for medications for depression at another clinic. During the wait for ADAP, before the patient assistance programs kicked in, I was in limbo for a month or so. I was approved for one medication at a time through the patient assistance programs – they kind of staggered in. It's hard to tell how many patient assistance programs you've applied to unless you know which company makes each drug. And when you're sick, you really don't care. The letters would come, I'd glance at them and then file them or throw them away. All of the drug company programs were about the same except that some took longer than others. You don't really know where the delay comes in – the company, the caseworker at the clinic, or somewhere in-between.

“This disease is most devastating to people with little knowledge of a system that needs lots of fixing.”

With symptoms of pneumonia (a dry cough and loss of appetite), major depression, and not knowing exactly what a case manager's role was, obtaining the needed meds was tedious and disorienting. I dealt with a confusing system, going from clinic to pharmacy to ASO to the local social service agency feeling like crap, always on the verge of either throwing up or running to the bathroom.

What was most disheartening for me was that I was already sick, confused, and uncertain how my diagnosis of *Pneumocystis* pneumonia (PCP) was going to play out, knowing that particular opportunistic infection had caused many deaths. I couldn't get the medicine I needed and worried myself into a frenzy.

Luckily for me, persistence paid off and I learned how to use the system. But I have friends and associates who haven't been as lucky due to lack of knowledge.

When my closest friend here in Charlotte was recently diagnosed, I went the same route for him, and the wait was even longer. Now I advocate for people who have to use ADAP and use the insight I gained to help others who aren't as knowledgeable about the system as I've become. The economics of the state of North Carolina and the Piedmont region I live in also contribute to the problems. In this area, when someone is diagnosed with HIV, prescribed a regimen, and insurance isn't there, you have to rely on the drug company programs or donations for medications from some charitable organizations until you move up the ADAP waiting list.

But what is one to do when you may have to wait for ADAP and the drug company programs and you're sick at the same time? Due to a lack of jobs in the rural areas, there aren't enough charitable contributions to go around for medicines.

I've seen people get sicker while on the ADAP waiting list.

My advocacy work today is meant to help lighten some of the worry for people in similar situations and help educate the government about the need for access to these meds right away. Believe me, those waiting lists can mean the difference between life and death, especially for people who are diagnosed with an opportunistic infection at the same time that they test HIV-positive.

I learned a lot about advocacy when I participated with Save ADAP in February, lobbying Congress for more funding. Save ADAP is a grassroots organization made up of people from across the United States who lobby Congress and state legislatures to adequately fund ADAPs throughout the country. We send letters to our state and national representatives asking for funds to eliminate these waiting lists, make telephone calls to their offices, and take trips twice a year to lobby our representatives' and senators' offices in person. To join Save ADAP, go to the website (atac-usa.org/adap.html).

The most important thing I've learned is that this disease is most devastating to people with little knowledge of a system that needs lots of fixing. Without adequate funding, a good case manager, or someone to go the distance for the less fortunate, there will be many unnecessary deaths from HIV/AIDS.

I'm doing okay now, healthwise anyway. My CD4 count is above 300 – higher than it's been for a good eight years or more – and my viral load is undetectable. I still take my meds (with never-ending side effects) and haven't been hospitalized. I now have Medicaid, which makes it easier to get the medicines I need.

It hasn't been HIV that has caused me the most harm, it's been the bureaucracy of HIV/AIDS – ADAP, Medicaid, housing, and Social Security (I'm still waiting after applying two years ago). And the solution is more funding for these programs. Hopefully some change will come about. This is what I pray for – CHANGE.

Henry E. Dendy is an HIV/AIDS educator and advocate living in Charlotte, North Carolina. He advocates with SAVE ADAP, works with the local Community Planning Group (CPG), the local consortium, and various local, and regional speakers bureaus.

The Ryan White CARE Act: AIDS is Still an Emergency

by Robert Cordero

Over a decade and a half ago, America and the world were introduced to a courageous young boy with AIDS named Ryan White. He was from Kokomo, Indiana and had been infected with HIV as a result of the blood product transfusions required to treat his hemophilia. The public discrimination that he faced transformed his life and the lives of others living with HIV and AIDS forever. Ryan made it possible for many Americans to understand the struggle to battle HIV and its accompanying stigma. He was truly a champion for that time in our history.

In testimony before the President's Commission on AIDS in 1988, Ryan (pictured at right) stated, "Because of the lack of education on AIDS, discrimination, fear, panic, and lies surrounded me. I was labeled a troublemaker, my mom an unfit mother, and I was not welcome anywhere. People would get up and leave so they would not have to sit anywhere near me. Even at church, people would not shake my hand. This brought on the news media, TV crews, interviews, and numerous public appearances. I became known as the AIDS boy. I received thousands of letters of support from all around the world, all because I wanted to go to school." He passed away two years later.



In 1990, the bipartisan Ryan White Comprehensive AIDS Resources Emergency (CARE) Act was finally signed into law after years of silence and inaction at the federal level on what was originally called Gay Related Infectious Disease (GRID) by the Centers for Disease Control and then renamed Acquired Immune Deficiency Syndrome, or AIDS, in 1982.

What the CARE Act Does

At this point in history, it is clear that the Ryan White CARE Act remains the nation's most important response to the AIDS epidemic. The CARE Act funds treatment for individuals living with HIV who lack health insurance and financial resources for their care. CARE Act programs serve 533,000 individuals in the United States and its territories each year, over half of whom live below the federal poverty level. Outpatient medical care and support services are the primary focus of the legislation, but training, technical assistance, and demonstration projects are also funded (for more detailed information on the Ryan White CARE Act go to <http://hab.hrsa.gov/history.htm>). The funding allocated for the

(continued on next page)

Ryan White Care Act *(continued from previous page)*

CARE Act in fiscal year 2004 was slightly over \$2 billion. Unfortunately, during the last four years, Congress hasn't increased funding, or flat-funded, the program, except for meager and insufficient increases to the AIDS Drug Assistance Program (ADAP). As funding has continued to erode, local and State budgets have become strained with increasing caseloads and high demand for HIV medication, care, and supportive services. Meanwhile, the patience of AIDS advocates with the government's response to the AIDS epidemic has worn thin.

Advocacy and Media Response

On August 30, 2004 thousands of activists chanted, "Fight AIDS!" during the *Still We Rise* march from Union Square to Madison Square Garden in New York City, site of the Republican National Convention – demanding that President Bush and the Republican Party focus on the problems of HIV, poverty, health care, and education in the United States. Another demonstration in front of Madison Square Garden grabbed front page headlines, with full color pictures of starkly naked members of ACT UP, messages stenciled to their bodies calling for the cancellation of debt from developing countries so that they might invest adequate resources to fight the global AIDS epidemic. In Bedford Stuyvesant, Brooklyn, angry community members living with HIV/AIDS protested against Senator Rick Santorum's (R-PA) abstinence-only policies during his visit to a community health center to discuss AIDS issues. On the final day of the Republican National Convention, hundreds of protesters took over Grand Central Terminal during a rush hour civil disobedience to oppose this Administration's apathy toward the domestic AIDS crisis. Nineteen protesters who surrounded the Grand Central Terminal information booth and a few who hung large banners from above the terminal stairwell declaring "America has AIDS" were arrested.

Despite local and national media attention from these and countless other demonstrations, the media rarely discussed the message and, instead, focused on the arrests. Political activism and civil disobedience as well old-fashioned advocacy and lobbying have all attempted to keep domestic AIDS issues in the collective public mind as a high priority among many other competing priorities like the war on terrorism and homeland security. So, what will it take to get through to this President, other legislators, and many of our fellow Americans that AIDS is still a crisis in this country? How do we invoke the spirit of Ryan White which had previously led to America's focus on our own AIDS epidemic in the late 1980s and early 1990s?

The Domestic AIDS Crisis

We often hear from our colleagues in Congress and the Administration that they don't hear from the AIDS community like they used to. The only AIDS-related messages that get through, if any, relate to the global AIDS epidemic in Africa and the Caribbean. Somehow, the domestic advocacy that created the Ryan White CARE Act has diminished, and the voices of people impacted by HIV in the U.S. aren't being heard. The media no longer covers national AIDS issues with the same vigor. It's almost as if AIDS has become the silent epidemic it once was, at the expense of our most vulnerable communities.

These include the HIV-positive African American woman with AIDS who pays her bills and works to support her kids in Biloxi, Mississippi; a recently infected homeless youth scoping out the scene and hanging out with friends in New York City's West Village; and the newly arrived immigrant in Portland who works the night shift and became infected through sex with an HIV-positive man – even though he doesn't consider himself to be gay. This slice of AIDS in America is only an illustration of the over 40,000 new HIV infections that we see in the U.S. each year, and the Ryan White CARE Act touches most of their lives at some point in their care.

Protecting AIDS Services in the U.S.

The CARE Act is the safety net by which we can assure that HIV-positive people have access to adequate medical care and the critical supportive services that get them into care and keep them there. As

the board Chair of the CAEAR (Communities Advocating Emergency AIDS Relief) Coalition, Patricia Bass, is known to frequently relate to congressional staffers, "HIV medications don't come out of a vending machine." The CARE Act has provided, in most instances, the only service system which enables people living with HIV to access medical care because their case management, housing, nutrition, substance use, and mental health needs are being addressed. The entire CARE Act – Title I, Title II, Title III, Title IV, Part F: SPNS (Special Projects of National Significance), Dental Reimbursement, and AIDS Education and Training Centers (AETC)– works in tandem with other HIV/AIDS funding streams to create a sustainable system of care that will collapse if under-funded.

Since the passage of the Ryan White CARE Act in 1990, countless AIDS activists have passed away, yet the soul of their advocacy is not dead. For example, Keith Cylar, Co-Founder and Co-President of Housing Works in New York City, died in April of this year but lived every day of his life reminding us that we must respond to the

"Thousands of activists chanted 'Fight AIDS,' demanding that President Bush focus on HIV, poverty, healthcare, and education in the United States."

needs of people living with AIDS and HIV, just as Ryan White did. “Making sure that we were going to stop this government, changing the way this epidemic was killing us. Life could not just go on as usual as long as we were suffering, as long as our friends, our lovers, and our sisters, our brothers were dying,” said Mr. Cylar in 2003. Keith and so many of our community heroes played a leading role in the development of federal legislation to create and fund HIV/AIDS service programs, including the Ryan White CARE Act. Their legacy of action reminds us that the struggle to enhance the nation’s response to AIDS is embodied in the importance of the Ryan White CARE Act as a linchpin of the public health infrastructure for people living with HIV/AIDS.

2005 Reauthorization

Since the Ryan White CARE Act was enacted in 1990, it has been reauthorized and signed into law twice by Congress, in 1996 and in 2000 – always passing by unanimous votes in the House of Representatives and the Senate. Authorization of legislation expands and creates programs such as the CARE Act. The CARE Act is due to expire on September 30, 2005. It is timely that this article appears in *ACRIA Update* now, with a one year deadline looming for the hopefully bipartisan reauthorization of the CARE Act for an additional five years. Our President may have the unique opportunity to demonstrate clear leadership on domestic AIDS by signing the reauthorized CARE Act into law in 2005.

In a prelude to his thinking on the Ryan White CARE Act, President Bush surprised many members of the AIDS community with his comments regarding the global and domestic AIDS crises at a church in Philadelphia on June 23, 2004. It’s widely known that the President embraces faith-based initiatives and abstinence-only policies, yet it may be less widely understood that he has not proposed increased funding for successful and effective domestic programs like the Ryan White CARE Act. In his speech that day, the President identified areas of focus for the Ryan White CARE Act that grassroots advocates, providers, people living with HIV/AIDS, and government officials need to be aware of as we prepare to formulate potential changes to the CARE Act to make it more responsive to the emerging needs of the AIDS epidemic in 2005 and beyond. President Bush stated, “When the Ryan White CARE Act is reauthorized next year, I propose to make it stronger and more effective by focusing resources on life-extending care, such as antiretroviral drugs and doctor visits and lab tests. This kind of care was just a dream 20 years ago. It is a reality today. And we will work with Congress to make sure that as many patients as possible are receiving the modern care they deserve. We need to change the way that money under the Ryan White CARE Act is provided to care-givers and states and communities. Today, funding decisions are made according to a rigid

The Ryan White CARE Act What Each Section of the Act Covers

Title I provides assistance to Eligible Metropolitan Areas (EMAs) with the largest numbers of reported AIDS cases to meet the emergency primary care and supportive service needs of people with HIV.

Title II provides funds to States and territories for primary health care, including medications through the AIDS Drug Assistance Program (ADAP) and to improve the quality, availability, and organization of healthcare and support services for people with HIV and their families.

Title III supports medical care and early intervention services to people with HIV through grants to public and non-profit organizations such as Community and Migrant Health Centers.

Title IV supports services and access to research for children, youth, and women with HIV and their families.

Part F:

- **AIDS Education and Training Centers (AETC)**, regional centers that offer trainings for healthcare providers and other people who provide AIDS-related services;
- **Special Projects of National Significance (SPNS)**, a health services demonstration, research, and evaluation program to identify innovative models of care; and
- **Dental Reimbursement Program**, which helps cover dental expenses incurred by people with HIV that aren’t otherwise covered.

geographical formula that takes too little account of the most urgent needs. In other words, you can’t set priorities – that’s what that means.”

Community advocates agree that the CARE Act must be reauthorized. The Ryan White CARE Act is one of the only pieces of health legislation that mandates a community planning process (for 51 eligible metropolitan areas) and coordination with other healthcare systems. In a reauthorized CARE Act, control over local decision-making and service needs must not be lost to the federal bureaucracy, since local communities are in the best position to assess their own needs, prioritize services, and allocate resources effectively. Furthermore, proposing to focus resources, and the formula which distributes them, is ineffective at best if annual funding is not increased to meet burgeoning demand.

Defending and Enhancing the CARE Act

AIDS is still an emergency, especially among marginalized populations – low-income people of color, the homeless, drug users, women, gay men, and other populations. Rural communities and urban neighborhoods are disproportionately impacted. Political

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AIDS Drug Assistance Programs

A Promising Start, A Shaky Future

by Lei Chou

Finding out you are HIV-positive is a life altering experience, as anyone who has been through it can tell you. That future you thought was waiting down the road suddenly disappears. Priorities take a big tumble, fear and confusion reign. Living in the only industrialized country without universal healthcare, HIV-positive Americans must face an additional issue that few thought critical in the prime of their lives: access to healthcare. For people with no health insurance and who are unable to meet the stringent Medicaid eligibility restrictions, the AIDS Drug Assistance Programs, or ADAPs, offer a path to life-saving treatment few can afford on their own. ADAP clients are usually the first to testify to the significance of this program. It brings a glimmer of the future they once thought lost.

with the steady increase in new infections, ADAP has seen roughly 600 new enrollees per month nationwide in recent years. Today, nearly one in five of the HIV-positive Americans in treatment, close to 150,000 people, are enrolled in ADAP.

ADAP has matured alongside the evolving HIV epidemic with remarkable resilience and simplicity. Funded primarily with federal dollars which are allocated based on the number of people living with an AIDS diagnosis, each state-administered program must use the limited funds to best meet the needs of the growing uninsured. As the payer of last resort, ADAP's ability to fulfill its role is contingent on the size of the healthcare gap it is facing. Not surprisingly, states with a more generous Medicaid program and

adaptive the program has been in meeting the needs of the HIV-positive and uninsured, it is a far cry from a comprehensive and responsible public health measure.

Unlike the federal Medicaid entitlement program where funding follows program growth, ADAP funding must be allocated by the federal government each year. The program is only able to expand coverage to fill the healthcare gap and meet growing demand when adequate funds are made available, notably in the late 90's. But as the federal commitment to domestic HIV care flagged with the current administration, programs across the country suffered. Federal ADAP funding has fallen short of the projected need in the last four years, with the current fiscal year operating with a \$122 million shortfall, about 15% of the program budget.

*Was I deceiv'd, or did a sable cloud
Turn forth her silver lining on the night?
John Milton, Comus*

ADAP first came into being in 1987, when AZT was approved by the FDA to treat HIV. At a cost of \$10,000 per year, advocates petitioned Congress to help pay for the expensive drug. In 1990, the program was included in the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, becoming the centerpiece of the nation's HIV care infrastructure. It remains one of the more successful responses to the HIV epidemic by the federal government.

Over the years, ADAP slowly expanded to cover treatment and preventive medicine for opportunistic infections and other conditions. With the approval of protease inhibitors in 1996 and Highly Active AntiRetroviral Therapy (HAART), the demand on ADAP nearly doubled in one year as people presented themselves for testing and sought treatment. As the number of AIDS deaths plummeted, people stayed in the program and the demand grew. Coupled

better healthcare system do better. The local economy also plays a role, determined by the number of jobs that include health benefits. Political priorities also come into play, demonstrated by each individual state's willingness to allocate state funds to the program.

Due to all of these reasons, each ADAP's eligibility criteria and the number of drugs they cover vary greatly from state to state. Annual income eligibility caps range between \$12,000 and \$50,000, differences in formularies range between unlimited drug coverage to antiretrovirals only, with one state not even providing protease inhibitors. While there are ongoing debates on how to resolve these disparities in access to HIV care, it is important to note that ADAP is still an emergency healthcare program, even as we cross into the third decade of the epidemic. The program's shortcomings are but a reflection of the state of healthcare in this country. However

In this climate of under funding, for the first time ADAPs are having a hard time meeting their core function: providing antiretrovirals. Nearly two years after its approval, the entry inhibitor Fuzeon is still not available in some states, due primarily to its exorbitant cost. Clients co-infected with hepatitis C are also having similar problems accessing pegylated interferon. Several states have eliminated critical prophylaxis and treatment agents for opportunistic infections and drugs that manage treatment side effects. Other cost cutting measures such as prior authorization and the strict enforcement of medical criteria are popping up in many states, creating barriers to care that disproportionately affect those people who are worse off.

The most visible symptoms of the ADAP crisis are the waiting lists. As of September, ten states had closed their programs to new applicants, relegating more than 1,600 people to wait for medications just five months into the current fiscal year. By the end of 2004, half of the programs in the country will likely close enrollment and/or implement more program restrictions.

While President Bush promised \$20 million dollars in June to remedy the waitlist crisis, three long months later the administration has yet to come up with a way to translate this funding into access to treatment. For fiscal year 2005, the President has proposed only \$35 million of the projected \$217 million increase needed to adequately fund ADAP. As of this writing, the prospect for ADAP is tenuous.

One group that is working to end this crisis is the Save ADAP Committee of the AIDS Treatment Activists Coalition. The committee functions via an email list serve and monthly conference calls, generating action alerts to advocate for ADAP funding and press releases to call attention to the crisis. Save ADAP members are composed of ADAP clients, frontline caseworkers, policy advocates, and even ADAP administrators. The group has organized two constituent visits to Capital Hill this year, bringing people from across the country to tell their legislators about the importance of ADAP. The stories they tell are about coming back from the brink of death thanks to a program that was there when they needed it. They are about picking up the pieces and moving on again once they regained their health and hope and got another chance. They are about making sure that someone else in their shoes will have the same opportunity when they need it.

ADAP was born out of a public health emergency. Seventeen years after its founding, the emergency is no less urgent. The program's existence and well-being depends on the AIDS community's commitment to hold our government accountable for the healthcare for those in need. The struggle continues.

To join Save ADAP and find out more about the group, please visit www.atac-usa.org/adap. For more information about ADAP, please visit the ADAP Monitoring Project: www.atdn.org/access/adap/index.html.

Lei Chou is the Director of The Access Project at the AIDS Treatment Data Network and a member of Save ADAP.

Ryan White Care Act *(continued from page 11)*

will be needed to effectively address the epidemic, and that must begin with the CARE Act. Due to woefully inadequate annual AIDS funding from Congress, it can be tempting to focus on fixing all of the problems in our healthcare for people living with HIV/AIDS through legislation like the Ryan White CARE Act. But the CARE Act is not a panacea, and advocates must continue to focus on improving it through the reauthorization process. This is a unique opportunity to retain what works while improving the legislation to be more responsive. National AIDS advocacy organizations are currently developing specific policy positions which may impact on the reauthorized CARE Act, and we should engage in these federal advocacy efforts at all levels.

There are also other proposals like the proposed Early Treatment for HIV/AIDS (ETHA) bill and, more recently, the Institute of Medicine Committee's proposed HIV Comprehensive Care Program (HCCP). But at this point, the Ryan White CARE Act (supplemented by an inadequate Medicaid system for the poorest Americans) is as close as we get to effectively address and fund the domestic AIDS crisis. **AIDS is still an emergency and the CARE Act responds to this emergency.** Without further funding, it will be unable to do so.

At minimum, the CARE Act needs to be protected. No other piece of domestic legislation has ever received as much scrutiny as the Ryan White CARE Act, with several audits by the Government Accounting Office (GAO) and the Health and Human Services Office of the Inspector General (IG). This doesn't even include congressional inquiries and other highly subjective CARE Act critiques by government reform "think tanks." Generally, Ryan White providers and government grantees have welcomed any and all efforts to demonstrate program accountability, and the CARE Act has held up well in these audits and reviews. As we move towards the expiration of the amended CARE Act of 2000, the community must be diligent in its efforts to ensure that amendments to the CARE Act of 2005 protect the integrity of the current Act while enhancing the system of care which has taken a decade and a half to develop. Clearly, the CARE Act will continue to be effective and accountable.

Let Congress and the President know in no uncertain terms – **PROTECT THE RYAN WHITE CARE ACT BECAUSE AMERICA STILL HAS AIDS.** Respond to the AIDS crisis in the nation. Provide much needed increases to the CARE Act and reauthorize the CARE Act in 2005.

Robert Cordero is the director of federal advocacy at Housing Works, the largest community-based, minority controlled HIV/AIDS agency in the country, and serves as a board member of CAEAR Coalition, which advocates for Title I and Title III of the CARE Act.

*“Bush’s plan...
to focus
resources,
and the formula
that distributes
them, is ineffective
at best if annual
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increased to meet
burgeoning
demand.”*

Food and Drug Administration *(continued from page 4)*

What is accelerated approval? Which drugs get it? Why? How does it work?

The best way to ensure that all HIV-positive patients had access to promising anti-HIV drugs was to focus on getting them through clinical trials and the FDA approval process as quickly as possible. In short, accelerated approval would benefit everyone: HIV-positive people in desperate need of new treatments, doctors without the time or resources to participate in expanded access programs, and pharmaceutical companies attracted to the idea of being able to cash in on their product much earlier in the drug development process.

Typically, an investigational drug for a life-threatening disease needs to show that it actually helps people live longer lives with less illness – **clinical markers** of effectiveness – than people taking either a placebo (a dummy pill) or a currently available treatment. Studies to test this are usually very large and often need many months or years of follow-up data to yield the necessary results. Fortunately, around the time activists and doctors were clamoring for the rapid release of new therapies, researchers found that certain laboratory parameters – **surrogate markers** of effectiveness – could be used to determine if a new therapy was likely to work without having to conduct time-consuming clinical marker studies. The first surrogate marker was the CD4+ cell count, whereby a sustained increase in CD4+ cells was found to be associated with longer survival. Then came viral load, whereby low or undetectable HIV levels in the blood translated into a higher likelihood of CD4+ cell recovery and longer, healthier living. The availability of these surrogate markers has enabled the FDA to review and approve investigational anti-HIV drugs on an accelerated basis.

When the accelerated approval guidelines went into effect in April 1992, a pharmaceutical company was technically allowed to file an NDA after the comple-

tion of Phase II studies that showed a positive effect on CD4+ cell counts in patients failing available options at that time. However, in exchange for accelerated approval, the company still had to conduct Phase III clinical trials to demonstrate fewer AIDS-defining illnesses and fewer deaths.

Today, the FDA rarely requires data from clinical trials employing clinical markers when reviewing investigational anti-HIV therapies given the overwhelming evi-

*“Unfortunately,
many
manufacturers
make
unsubstantiated
marketing claims –
untested
supplements
to cure or treat
HIV remain
popular...”*

dence that improvements in CD4+ cell counts and reductions in viral load are associated with longer, healthier survival. The agency – and ADAC – usually like to see at least 48 weeks of CD4+ cell count and viral load data from a sizeable study involving patients who desperately need new treatment options before they will grant accelerated approval. Phase III studies must also be well underway before an NDA seeking accelerated approval is reviewed. And while the FDA may no longer require Phase III studies to look for differences in death rates or the number of new AIDS-related illnesses, the accelerated approval guidelines permit the FDA to demand additional data

from the company, such as longer-term safety and effectiveness research (longer Phase III follow-up or the addition of Phase IV studies, for example).

What about “standard” and “priority” review? Is this the same as accelerated approval?

No. With accelerated approval, the drug company begins working with the FDA early on in the development process so that an NDA can be submitted for review after the completion of Phase II or early in Phase III. For some drugs, the FDA requires completed data from Phase II or III studies before the NDA will be reviewed. However, there is still a way to accelerate the process: request that the FDA grant a **priority review**.

A standard review is given to drugs that provide only minor or no improvement over currently available options. A priority review can be granted to drugs that are likely to provide a significant advantage over currently available options. A standard review means that the FDA can take as long as 12 months after the NDA is submitted to review the data and grant approval. With a priority review, the FDA calls on a larger number of staff to review the NDA, reducing the approval time to less than six months.

What’s the deal with FDA regulation of herbs, vitamins, and complementary therapies?

Herbal products, vitamins, and other complementary therapies are classified as dietary supplements in the eyes of the FDA. They are not considered drugs and, therefore, are not regulated by CDER. These products are regulated by the FDA’s Center for Food Safety and Applied Nutrition (CFSAN), using guidelines stemming from the Dietary Supplement Health and Education Act (DSHEA) of 1994.

Generally speaking, dietary supplements – a catch-all term for any vitamin, mineral, herb, botanical, amino acid, or other dietary substance (such as enzymes or

tissues from organs or glands) – are largely unregulated. Manufacturers do not need to obtain approval from the FDA or prove that their product is safe or effective before selling it to the public. The FDA can only intervene in the sale of dietary supplements under two conditions: 1) if the drug is found to be toxic or unsafe, relying on reports filed with the agency by doctors or consumers; and 2) if the manufacturer makes claims that the product has medicinal value (meaning that it can be used to diagnose, cure, mitigate, treat, or prevent a disease). Unfortunately, many manufacturers *do* make unsubstantiated marketing claims – untested supplements to cure or treat HIV remain popular – which has contributed to the ongoing debate as to whether the FDA should have more power, not less, in regulating the sale of these products.

Summary

The activities of the FDA since the beginning of the AIDS epidemic a little more than 20 years ago have been nothing short of amazing. The regulatory role of the agency has been tugged in all directions – by politicians, by researchers, by the pharmaceutical industry, by activists, and by consumers. But through it all, the FDA still has a lot to show for itself: the approval of 26 anti-HIV medications, including 19 unique agents, three prodrug/extended-release formulations of older drugs, and four fixed-dose combinations. Not to mention numerous drugs for AIDS-related conditions. No other disease has ever seen this number of FDA approvals in such a short period of time. This may not have been possible without the flexibility the FDA has shown. And it definitely wouldn't have been possible without the dedicated individuals – AIDS activists, healthcare providers, and people with HIV – who worked tirelessly, both with and often against the FDA, to make this a reality.

Tim Horn is Executive Editor of The PRN Notebook, published by Physicians' Research Network in New York. He is also the head medical writer for AIDSmeds.com.

Patient Assistance Programs Getting Free Drug from the Drug Makers

by Brian D. Klein, MA, LMSW

The ever-escalating costs of many prescription medications have created barriers to accessing necessary treatment for people who are uninsured, underinsured, and/or have a low income. The somewhat negative term often used to refer to folks in this category is “medically indigent.” More Americans are falling into this category each year, with 15.6 percent of the U.S. population (45 million people) uninsured as of 2003 according to the U.S. Census Bureau. It can be argued that the pricing practices of the pharmaceutical industry have helped to create this situation. But industry has also created a response to the problem by creating Patient Assistance Programs (PAPs).

What are Patient Assistance Programs?

Patient Assistance Program are drug company plans that provide free medications to low-income, uninsured, and underinsured people who need them.

What's the history of these programs?

It isn't clear precisely how or when these programs started, but with the approval of more expensive treatments for such serious and chronic illnesses as cancer, viral hepatitis, and HIV over the past twenty-five years, these programs have grown as well. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the primary representative and lobbying organization for the pharmaceutical industry, 6.3 million Americans were served by PAPs in 2003. No one can really say how much money in “donated” medications was actually spent on these patients. Each drug company puts out its own public relations figures to demonstrate the extent of its philanthropy through these programs. These figures are often calculated using the inflated retail cost of the drug, a figure that no one really pays and is certainly far higher than the actual cost to the company of manufacturing and distributing the drug.

Who is eligible to participate in PAPs?

Each program is somewhat different, so always contact the PAP directly for its specific eligibility criteria. The following are general guidelines for most programs:

- You must be a U.S. citizen or legal resident.
- You must have a doctor or other healthcare provider who can write prescriptions and treat you.
- You can't have any health insurance that provides prescription coverage.
- You can't be eligible for Medicaid, Medi-Cal (in California), ADAP (AIDS Drug Assistance Program), or any other drug assistance program.
- You must meet the annual income limits of the specific program.

How do I prepare for application to a PAP?

You don't have to do this alone. It's hard enough having a serious or chronic illness. It can be helpful to have a social worker, benefits counselor, healthcare professional, friend, or loved one help you with the application process. Before you call the PAP, have as much information at hand as possible. This will help speed up the process and your peace of mind. Below is a helpful checklist. The more of this information you have prepared, the better.

- Know the name of the prescription drug you need.
- Know the name of the company that manufactures the drug. This information will help you locate the specific patient assistance program you need.
- Have general information on hand, such as your name, social security number, address, state of residence, and citizenship/residence status.
- Be prepared with contact information for your doctor or other healthcare provider (the phone and fax number will help a lot).
- Have a copy of your Medicaid, Medi-Cal, or other insurance/drug coverage denial letter.

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Patient Assistance Programs *(continued from previous page)*

- If you're on an ADAP waiting list or your state ADAP doesn't cover the drug you need, have a letter or other documentation from the program explaining the situation.
- Be prepared to provide your estimated gross annual household income (copies of pay stubs, tax returns, etc.).
- Have proof (such as award letters) of any government income assistance: Social Security Disability Insurance (SSDI), Supplemental Security Income (SSI), or State Disability Income (SDI).
- Have proof of medical expenses that you have had to pay yourself, such as bills or receipts.

Are Patient Assistance Programs the same in every state?

In general, the rules are the same across the country. But if a drug is covered by another program in your state for which you are eligible, then the PAP will not cover that drug for you. The PAP rules are generally designed and adjusted to be the last resort for access to the medication.

Can immigrants (legal/illegal/undocumented) qualify for PAPs?

In practice, drug companies don't want to act as immigration police and usually don't check into these situations beyond what is stated on the form by the applicant. If you have a social security number, currently live in the U.S., and qualify in all other ways, you will usually be approved.

Do I need a healthcare provider before I contact a PAP?

Yes, you need a doctor or other healthcare provider who can legally write prescriptions. The application form almost always has to be sent or faxed to your healthcare provider to complete. Quite often, the PAP requires a healthcare provider to apply on your behalf. If your primary provider is a registered nurse (RN), nurse practitioner (NP), or physician assistant (PA), don't worry. They almost always work closely with a physician who can sign the forms if the PAP requires it.

Are there any medical eligibility requirements for PAPs?

Depending on the program, you might need to have a specific diagnosis relevant to the needed medication, verified in writing by your healthcare provider.

What if I have private insurance prescription coverage but it still leaves me with a big co-payment?

If you have health insurance that covers the drug, but leaves you with a large co-payment, you will not be eligible for the PAP. By federal law, patient assistance programs cannot cover co-payments.

What if I have private insurance with prescription coverage, but it only covers my medicine for a limited time?

If you have insurance that denies coverage of the drug or only

covers it for a limited amount of time, then a PAP will usually work to help you.

Can I qualify for a PAP while I am eligible for Medicaid and/or Medicare?

As of this writing in 2004, no one yet has real prescription drug benefits through Medicare. Medicare prescription discount cards don't count as actual prescription coverage, so you will still be eligible for a PAP if Medicare is your only insurance. On the other hand, if you have Medicaid (Medi-Cal in California) that includes prescription drug coverage for that drug, you will not be eligible for the PAP.

What if I am on a waiting list for ADAP (AIDS Drug Assistance Program)?

If you are on a waiting list for one or more HIV-related drugs covered by your state ADAP, the PAPs for those drugs will usually provide medication to you until your ADAP benefits begin. Unless all of your HIV medications happen to be made by the same company, you'll have to apply to the PAP specific for each drug you need.

May I use the PAP from one drug company to get my medication from a different company?

No. You can only get the medication you need from the PAP run by the manufacturer of each specific drug.

What is the general procedure to enroll in a PAP?

Most PAPs have a toll free phone number that you call to make the initial contact. Most of the people who answer the phones for these programs are more pleasant, sensitive, and better trained than in the past. When you contact them, most drug company PAPs have an application for you to complete in writing or over the phone to get general information from you including income and medical benefits. As stated earlier, the application form almost always has to be sent or faxed to your primary healthcare provider to complete.

Do I need to have a certain income level to qualify? Does what I have in the bank and/or assets such as a house or car affect my eligibility for PAPs?

Most PAPs no longer have restrictive asset limitations. Owning a home or a car, your bank account assets, and the like no longer disqualify you.

Most PAPs go purely by current income level. The Federal Poverty Guideline annual income level for an individual in the lower 48 states in 2004 is \$9,310. Rates vary but, realistically, most PAPs use between 200% and 350% of the poverty level (between \$18,600 and \$33,500) for current income eligibility. This may vary by region of the country and other circumstances, including the number of people in your household. (For a com-

“Most PAPs use between 200% and 350% of the Federal Poverty Guideline (between \$18,600 and \$33,500) for income eligibility.”

plete Federal Poverty Guideline Chart, including those for Alaska and Hawaii, go to: <http://aspe.hhs.gov/poverty/04poverty.shtml>.)

Drug companies are reluctant to give out exact income guidelines, presumably fearing that people may cheat to try to meet them. When pushed, some companies will state a specific percentage of the poverty guidelines. Practice has actually shown that most of the programs are quite flexible in terms of proof of individual circumstance, even if you're slightly over their limits. But be prepared to justify your current financial situation, including proof of medical expenses. PAPs aren't going to bail you out of credit card debt that is non-medical.

What happens if I work while receiving medication from a PAP?

Most PAPs are primarily concerned with your insurance status, and then with your income. As long as you have no insurance that covers the drug *and* your income is within the PAP's guidelines – regardless of the source – the fact that you are working shouldn't affect your eligibility.

How soon after applying will I be eligible for benefits from a PAP?

Each program is different. For every story of swift service of only a few days, there is a horror story of waiting several months to receive the needed medication. On average, it usually takes two to four weeks. Submitting all of your required information as quickly as possible and following up with your healthcare provider to make sure that their portions of the application have been completed will help speed up the process. *So advocate courteously - ly for yourself and keep after your provider if necessary.* Your healthcare team wants you to have your medications, too!

How do I stay enrolled/eligible in a PAP? How do I reapply?

Each program has somewhat different requirements that you must follow. Some require you to reapply each time you need a new prescription, but many require that you only reapply every three months, six months, or annually with a recheck of your income and other eligibility requirements. Be sure that you understand the provisions of the specific program.

So tell me how to contact these Patient Assistance Programs already!

Finding out how to contact a PAP has often been the hardest part about them! These companies are in business to sell drugs, not give them away, so there is very little printed information available about these programs. There is often little on the actual drug companies' websites either. Because of the amount of paperwork and follow-through required by the healthcare providers, they sometimes don't keep on top of everything.

Patient Assistance Programs Useful Internet Resources

The Access Project of AIDS Treatment Data Network

www.atdn.org/access/pa.html

This organization, which helps people with HIV access treatment, has a web page dedicated to up-to-date information on Patient Assistance Programs, particularly for drugs used to treat HIV, hepatitis C, hepatitis B, and opportunistic infections related to HIV. Scroll down the page and click on the name of the drug you need, and you will be linked to a page with the corresponding company name, contact information and general eligibility requirements for that company's Patient Assistance Program.

PhRMA (Pharmaceutical Research and Manufacturers of America)

<https://www.helpingpatients.org/Intro.php>

If a drug you need isn't listed on The Access Project, here's another source to try. Surprising as it may seem, this lobbying organization for the drug industry has easy-to-use, up-to-date contact information for all of the different Patient Assistance Programs offered by its members. The best way to use the site is to know the name of the drug you need and the name of the company that manufactures it.

ACRIA www.acria.org

As an online addition to this issue of *ACRIA Update*, our website includes a list of the PAP contact information for the most commonly used medications for HIV, hepatitis C, hepatitis B, and AIDS-related opportunistic infections.

WARNING

There are a few sites on the Internet that offer to help you apply to any drug company Patient Assistance Program you need. Some of them charge a small fee that may or may not be refunded to you. Some of these sites are run by perfectly reputable folks, but others aren't. It's probably best to skip them all together. They usually create extra steps for you. They can only use the exact criteria that the drug companies provide. You will be far better off applying directly to the PAP yourself so that you can explain your individual situation as necessary.

Some companies consolidate their various drug products into one PAP. Others have different programs for each drug or each set of drugs for a specific disease. Some programs have catchy names (such as Boehringer Ingelheim Cares Foundation, Glaxo SmithKline's Bridges To Access Program, and Schering-Plough's Commitment To Care Program), slightly different requirements, and their own application form. It can be very confusing and, frankly, is often geared to make things difficult rather than easy.

Use the Internet resources listed above for the contact information for most Patient Assistance Programs that provide HIV-related medications. If you apply, don't get discouraged. Follow the steps suggested above, courteously ask for help, and follow-up with your healthcare provider and the PAP throughout the process. Hopefully, you can get the medication you need!

Brian D. Klein MA, LMSW is a former medical social worker and a founder of the Hepatitis C Action & Advocacy Coalition (HAAC). He is an advocate for people living with hepatitis C (HCV) and those co-infected with HIV and HCV.

Medicaid and Medicare *(continued from page 6)*

been challenging to protect services, particularly for low-income people, but the last four years have signaled that the administration would like to place restrictive limits on healthcare provision. There has been an active move to end the entitlement status of Medicaid as well as cut funding to the program. Although Medicare is more protected from the attempts to restrict services because of its role of serving more politically powerful seniors, the much touted prescription drug benefit, which will provide some relief, also carries great risks for most people living with HIV.

What's Happening in Medicaid – The Federal Level

The federal government matches state Medicaid spending with the Federal Medical Assistance Percentage (FMAP). FMAP, or the federal percentage, varies state to state and can be anywhere from 50 percent of overall spending for higher income states to 77 percent for lower income states. Matching rates can be higher for some services or programs. It is an open-ended match, meaning that as long as the state spends to provide services, the federal government matches that spending. This allows states to incorporate new technologies and drugs and respond to emerging epidemics and downturns in the state economy that lead to job and insurance loss.

In the past couple of years, the Bush Administration has tried to cap federal spending through a block grant or a set amount of money that would go to each state. The only way the state could respond to any program growth would be by spending state money. People with HIV and many others would suffer greatly under the enactment of block grants, likely losing services and even eligibility. Fortunately, Congress and governors have been concerned about the idea of block grants and the proposals have stalled.

In 2003, in recognition of states' fiscal crises, Congress passed a temporary increase in the FMAP, which ended in

June 2004. Forty-two states reported that the increase helped with their Medicaid increases, 27 reported that they avoided, postponed, or minimized program cuts, and all reported that the end of the increase will bring challenges. Legislation has been introduced that would renew this temporary funding.

What's Happening in Medicaid – The State Level

Since 2001, states have been experiencing various degrees of fiscal difficulty. For the past three years, growing Medicaid spending has been a target for states trying to balance budgets. In spite of the temporary increase in FMAP, 49 states started 2004 with plans for Medicaid cost containment and 18 planned mid-year cuts or cost containment measures. For people living with HIV and others, these measures can mean the loss of life prolonging comprehensive care. For example, Mississippi cut eligibility in a move that could mean that up to 65,000 disabled and elderly lose their coverage.

For advocates, fighting cuts at the state level has become a critical part of protecting Medicaid programs for people who need them. We also have to monitor waivers. States are allowed to submit waivers to the federal government that would remove some beneficiary protections, establish cost sharing obligations, allow changes in benefit packages, and make other important program changes. Waivers are often enacted with an eye to cutting or containing costs. When cutting costs is the primary goal, the outcome is likely to hurt people's healthcare. The waiver process is typically long and bureaucratic, but it is essential to follow and provide input.

What's Happening in Medicare

The most significant gap with Medicare coverage for people with HIV has always been the lack of a prescription drug benefit. The Medicare Modernization Act provided a drug benefit for Medicare that will be implemented as of January 2006. Unfortunately, the benefit was funded at significantly less than what would be

needed for complete coverage. In addition, the pharmaceutical industry lobbied successfully to include a ban on the federal government's ability to negotiate the price of drugs provided by the benefit. Therefore, the benefit will have restrictions that could compromise care.

The Medicare prescription drug benefit has many potential problems. The concerns that are most pertinent for people with HIV are included in *The Medicare Prescription Drug Benefit – Issues for People Living with HIV/AIDS*. You can view this document at www.projectinform.org/tan/0408mcpoints.html. Advocates are insisting on the creation of sufficient information for consumers to help them understand and utilize their benefit, implementation of a sufficient appeals process, and assurance that the formularies (lists of available drugs) are inclusive of necessary medications.

The regulations that will govern the benefit were in the public comment period until October 4th. The HIV Medicaid and Medicare Working Group, made up of national and regional HIV/AIDS organizations, issued comments and provided information to help other interested individuals and groups submit comments as well. To get more information on Medicare benefit advocacy, visit the HIV Medicine Association (www.hivma.org). To join the Work Group, email Project Inform's Treatment Action Network (tan@projectinform.org) or The Access Project (theaccessproject@aol.com).

Medicaid and Medicare are the backbone of HIV care. They are also the only attempt in the U.S. to provide healthcare for low-income and vulnerable populations. We can't allow the work of the last 30 to 40 years to protect the health of Americans to be rolled back due to misplaced political priorities. People with HIV and their advocates have to understand and fight for the programs we depend on.

Anne Donnelly is Public Policy Director of Project Inform in San Francisco.

ACRIA's Over 50 Research Receives National Media Attention

Two major media outlets have recently used ACRIA's research as the central resource to discuss the aging of the nation's HIV-positive population. On July 7, 2004, the cable channel CNNfn invited ACRIA's Associate Director for Research, Stephen Karpiak, Ph.D., to talk about this relatively unacknowledged issue during a 10 minute live broadcast. *The New York Times* subsequently described portions of ACRIA's seminal research on this topic in an August 17, 2004 article titled "Facing Middle Age and AIDS." Among other things, the front page article in the Science Times section described our findings on the high levels of depression in HIV-positive seniors and the population's relative lack of support from family and friends as they experience age-related health problems in addition to complications from HIV and AIDS stigma. The BBC also recently interviewed ACRIA researchers about our Research on Older Adults with HIV/AIDS (ROAH) initiative, which will be broadcast in the near future.

ACRIA's leading role in researching the needs and circumstances of the older HIV-positive population is an ongoing endeavor. We are currently recruiting for a major follow-up study that seeks to enroll 1,000 New York City participants. This new research will include the largest sampling of an older HIV-infected population so far accomplished. We expect its findings to substantially advance understanding of how the United States HIV population will age in the coming decade, and may significantly impact HIV/AIDS health policy.

TrialSearch Now Includes Information On Enrolling Studies Nationwide

In August, TrialSearch@acria.org achieved a milestone for this national online database of HIV/AIDS clinical trials. Information about HIV-related clinical trials in all 50 states and Puerto Rico is now available through this interactive database. This could not have been achieved without the help and dedication of a number of interns who worked with ACRIA over the summer. We continue to update the trial information on a state-by-state basis, and recruitment of volunteers is ongoing.



is looking for new COMMUNITY ADVISORY BOARD members.

ACRIA's Community Advisory Board (CAB) fosters partnership between the education staff and the local community impacted by HIV/AIDS. Involving community members in the development of our education programs ensures that community values and cultural differences are respected in ACRIA's educational work.

Community Advisory Board members meet every other month, review program materials and help us identify education needs.

For more information about the CAB or if you are interested in volunteering at ACRIA, please call Mark Milano at (212) 924-3934, ext. 123.

HONORING OUR HEROES

We'd like to honor two HIV community leaders who died recently, both of whom worked with enormous dedication for equitable access to care, treatment, and other necessary services for all people living with HIV – Charles Clifton and Keith Cylar.

Charles Clifton, Executive Director of Test Positive Aware Network in Chicago and Editor of *Positively Aware*, passed away on August 15, 2004. In addition to many other responsibilities, Charles was on the Steering Committee of the national AIDS Treatment Activists Coalition (ATAC) and has been instrumental in helping to organize the North American AIDS Treatment Action Forum (NATAF) for the last several years. Memorial donations can be made to The Charles E. Clifton Memorial Fund by sending a check made payable to Test Positive Aware Network, noting The Charles E. Clifton Memorial Fund on the check. Donations can be sent to:

Test Positive Aware Network (TPAN)
5537 N. Broadway
Chicago, IL 60640

Keith Cylar, Co-Founder and Co-President of Housing Works in New York City, died on April 5, 2004. The Keith Cylar Activist Fund establishes a continuing legacy to his life and work. The Fund will create a permanent endowment to support advocacy and activism by people living with AIDS and HIV in America and around the world. The Fund will provide people living with AIDS and HIV with training and continued support to enable them to be effective advocates who are fully involved in policy and decision making. To contribute, please go to www.housingworks.org/activistfund or send a check made payable to The Keith Cylar Activist Fund to:

Housing Works, Inc., Attn: Development
320 West 13th Street, 4th floor
New York, NY 10014

generous contributions

The following persons, corporations and organizations made major donations between June 16 and September 17, 2004 to support ACRIA's research and education efforts:

Alize	Calvin Klein
Banana Republic	Rainbow Endowment
Bristol-Myers Squibb Virology	Roche Molecular Systems, Inc. Louis & Rachel Rudin Foundation
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The Diller-Von Furstenberg Family Foundation	Until There's A Cure Foundation
Gilead Sciences	W Hotels
In Style Magazine	
Jewel of Russa Vodka	

Thoughtful donations were made in memory of the following individuals:

Barry Binkowitz	David Seidner
David A. Eklund	Robert L. Stipe
Helen Guberman	David Tamayo
Bennie W. Krueger Jr	Joseph John Tamburo
Vincent Lattuca	

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