

# wise words

## Is switching or stopping therapy right for you?

It has been four years since highly active antiretroviral therapy (HAART) has been around to treat HIV. Initially, there were hopes that powerful three-drug regimens would severely hinder HIV. While the health and lives of many people have dramatically improved from using these drugs, the unfolding realities of lifelong treatment remain a daunting challenge for many. The emergence of serious and troubling side effects, drug resistance, treatment failure and exhaustion from demanding pill requirements signals the need for an alternative to lifelong HAART.

Partly because of these and other concerns, some people are delaying treatment longer. And as less demanding combinations become available, many also consider changing regimens even though their current strategies may still be providing benefits. Others consider whether to stop treatment for a period of time (interrupting therapy) or to stop it permanently. And still others who have stopped or are thinking of stopping treatment wonder when and how to best resume therapy.

Fortunately, scientists are exploring these questions. They are asking whether switching and/or stopping therapy for a defined period of time works as a strategy to treat HIV. These strategies are being explored as ways to reverse or lessen risks for body shape changes (lipodystrophy), believed to be associated with certain anti-HIV drugs. Stop-



ping and switching treatment are also being evaluated for how they may lower the lab markers of increased risk of heart disease—triglyceride and cholesterol levels—which some anti-HIV drugs appear to elevate.

So far, results from the few conducted studies have been mixed (page 2). Despite the increase in research and media attention on these issues, there is still a great deal of confusion and concern about the risks of these approaches. There's also uncertainty about how to most safely use them. Without clear guidelines, people living with HIV and their doctors face tough decisions of whether and how to switch or stop anti-HIV treatment.

This article highlights some of what we've learned so far about this important emerging area of research. It also provides some basic guidelines on things to consider if and when you face these decisions.

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## a word from wise

If you are among the many HIV-positive women with questions about switching or stopping anti-HIV treatment, then this issue of *Wise Words* is written especially for you. It highlights lessons learned and provides basic guidelines for consideration if and when you should be faced with the decision to switch or stop. If you are not facing these decisions right now, or are not on anti-HIV treatment, chances are you may be examining these issues in the future. So hang on to this issue! And be sure to check out the upcoming *PI Perspective*, which will explore questions on starting therapy.

This issue of *Wise Words* is the product of conversations we have had with positive women across the country. You told us that this was an area of interest to you, and we did our research and wrote about it. What you think is important to us. That's why we hope you will take a few minutes and fill out (and mail!) the enclosed questionnaire. It will help guide future issues of *Wise Words*. Thank you!

*Angela Garcia*

Angela Garcia, Project Director  
Women's Education and Advocacy

### WHAT'S INSIDE WISE

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# Is switching or stopping therapy right for you? ... continued

## SWITCHING THERAPIES

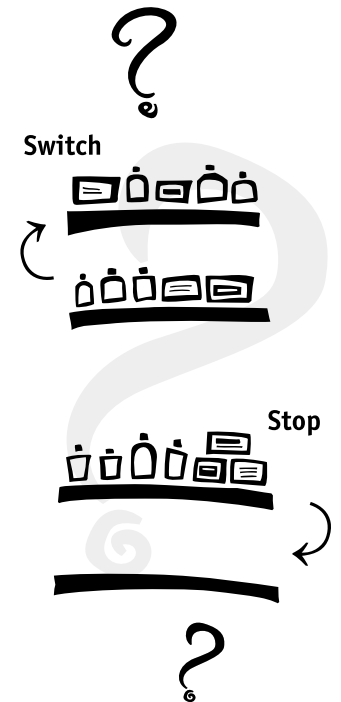
One consideration is whether to switch to a regimen without a protease inhibitor. Generally, such a regimen contains three nucleoside analogue reverse transcriptase inhibitors (NRTI) or two NRTIs and a non-nucleoside reverse transcriptase inhibitor (NNRTI). There also are times when people switch to two NRTIs; but this is not generally recommended because it does not suppress HIV long-term. What is definitely NOT recommended is switching to one NRTI and NNRTI each because of the high risk of drug resistance.

Another reason for switching drugs in a regimen is to lower cholesterol and triglyceride levels. These levels have been associated with anti-HIV therapy, especially protease inhibitors; and switching may be somewhat effective in helping to reduce them. However, there's conflicting information on whether switching helps reverse the fat redistribution in people with lipodystrophy.

People also consider switching therapies be-

cause of side effects or treatment fatigue. In either case, it's important to talk with your doctor to determine if switching is the best option. For instance, side effects may subside over time or they may be managed in other ways. For treatment fatigue, switching to a regimen with fewer pills or one that's less demanding in terms of timing and food restrictions may be a viable option.

Whatever the decision, talk with your doctor to jointly determine personal goals. Keep in mind that guidelines are important. For example, it's helpful to decide *before* switching treatment whether to aim for maximum viral suppression or whether other factors make this goal unrealistic or less important. Or, perhaps the primary goal is easing pill burden and side effects while maintaining CD4+ cell counts in a "safe" range and preventing disease progression. Whatever the decision, having clear goals in advance of a switch helps make future decisions easier.



## STOPPING THERAPIES

There is a great deal of interest, from patients, doctors and researchers alike, in evaluating stopping therapy. While the interest in Structured Therapy Interruptions (STI) may vary, everyone agrees that this approach needs to be seriously studied.

Stopping anti-HIV treatment on one's own, or taking a break on your own (*treatment holiday*), is not the way to approach an STI. Such breaks, taken every now and then—even for just a day or two—will almost certainly increase the risk of developing anti-HIV drug resistance, jeopardizing current and future treatment options. So let's be clear, stopping therapy on your own or taking a treatment holiday is **not** the same thing as an STI.

An STI includes stopping anti-HIV therapy for a defined period of time, usually at least a month or more. Depending on your goals, re-starting therapy is done on a specific time frame (e.g. start after one month) or based on certain criteria, such as viral load or CD4+ cell count changes.

*let's be clear, stopping therapy on your own or taking a treatment holiday is not the same thing as an STI*

These decisions are *strategic* and *structured*, made in partnership with your doctor and/or in a closely monitored study. It is important to monitor CD4+ cell counts and viral load more frequently while on the STI.

At this point, it's too soon to tell whether STIs will be beneficial or harmful. Serious risks have been seen in some studies, including CD4+ cell count losses that might not be regained after re-summing therapy; viral load increases that might not be brought back under control; and the risk of resistant virus emerging and taking hold after stopping therapy.

Because of these risks and many unknowns, it's advisable for people

interested in stopping treatment or STIs to seek out a study for guidance in decision-making and careful monitoring. Many studies around the country are exploring STIs. To learn about them, call 1-800-TRIALS-A, check out the website at [www.ClinicalTrials.Gov](http://www.ClinicalTrials.Gov), or request Project Inform's materials on STIs by calling our toll-free Hotline at 1-800-822-7422.

### Goals of STIs

**In general, the current goals behind STIs focus around three basic theories:**

**1**

STIs may preserve or strengthen immune responses against HIV, primarily studied in people with very early infection.

**2**

STIs may restore a useful degree of sensitivity to anti-HIV therapies in people who are resistant to several different ones.

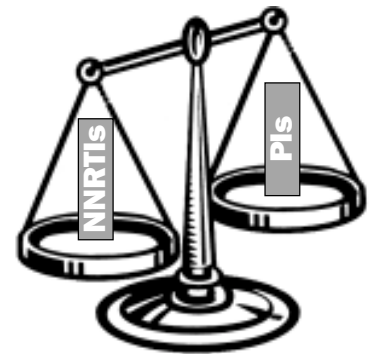
**3**

STIs may give people experiencing treatment fatigue or severe side effects a break from therapy long enough to permit some degree of healing, both physically and psychologically—if it can be done without creating long-term harm.

Recently, there has been a lot of talk about switching from a protease inhibitor-based regimen to a non-nucleoside (NNRTI)-based regimen. Why is there so much interest in doing this? Should I consider switching to an NNRTI-based regimen?

## protease inhibitors vs. nrtis

Interest in switching from a protease inhibitor-based regimen to an NNRTI-based one is largely motivated by concerns about protease inhibitor side effects and about saving the protease inhibitors for later use when disease progression might require the strongest approach to treatment. With either approach, almost all such regimens include two NARTI (nucleoside analogue) drugs.



Generally NNRTIs have fewer side effects than protease inhibitors. Two big side effect concerns with protease inhibitors that often motivate switching therapy are fat redistribution resulting in a change in body shape composition (*lipodystrophy*) and abnormal changes in lab values, including triglycerides and cholesterol. This is seen in some people on long-term protease inhibitor therapy. However, it has still not been definitively shown that protease inhibitors are the cause or sole cause of lipodystrophy, nor is there any strong evidence that switching to an NNRTI-based regimen will correct the problem once it occurs.

A lot of research has looked at the effects of switching from protease inhibitor to NNRTI regimens on lipodystrophy. Some protease inhibitors, especially ritonavir, can significantly increase triglyceride and cholesterol levels that may increase the risk for heart disease. Study results so far suggest that changing regimens does not reverse fat redistribution, but triglyceride and cholesterol levels are decreased especially if the NNRTI is nevirapine (Viramune).

There are conflicting results on whether efavirenz (Sustiva) decreases these levels. So it might be reasonable to switch to an NNRTI-based regimen if your cholesterol and triglyceride levels are elevated. However, it is also possible to use cholesterol and triglyceride lowering drugs to achieve the same effect, although drug interactions may occur between these drugs and the protease inhibitors.

Another factor that leads some people to switch from protease inhibitor to NNRTI regimens is that most NNRTIs have relatively easy dosing. Fewer side effect and better ease of use lead some to believe that adherence (taking drugs as prescribed) will improve and thus increase the chances of long-term success.

The decision to change your anti-HIV regimen is best made in partnership with your doctor. Many experts believe that if you experience a good response (suppressed viral load and increases in CD4+ cell count) with minor or at least tolerable side effects on a protease inhibitor-based regimen, then it's reasonable and maybe even preferable to continue on that regimen. There is always a risk, whether from side effects or diminished response to therapy, with switching regimens.

### A NOTE ABOUT NNRTIS

The dosing advantage of the NNRTIs has been diminished recently with the use of low dose (sometimes called *baby dose*) ritonavir (Norvir) in combination with another protease inhibitor. This results in higher and more sustained levels of the other protease inhibitor in the blood. Therefore it's possible to use lower doses of both drugs and the schedule can be reduced to twice-a-day and possibly even once daily. However, this combination may not be an option for everybody.

## THE BOTTOM LINE

It is unrealistic for most people to take medication every day, for the rest of their lives. Fortunately, simplified and easier-to-use anti-HIV therapies are becoming available (see *Odds and Ends*, page 6). But switching therapies for the sake of fewer pills and side effects may not be the answer for everybody. New approaches for treating HIV are clearly needed.

Currently, there are no clear guidelines on switching or stopping treatment. Like any other treatment decision, learning about your options, talking to your doctor and carefully weighing the pros and cons of switching or stopping treatment therapy may be the best guidance.

For those who take preventive therapies for opportunistic infections, or medications to manage other conditions, STIs do not include stopping those therapies. Close monitoring is also essential as it lessens potential risks.

Finally, for those who have decided to switch or stop therapy, this might be most safely done in the context of a clinical study. Studies provide more intensive monitoring, lessening the risk to you. They also result in information that will help others facing the same decisions in the future.

... more real life situations ...

## O.I.s

**My doctor recently told me that I can stop taking my opportunistic infections (OI) preventive therapies. Does this mean that I can also stop taking my anti-HIV drugs?**

It's likely that your doctor told you that it is safe to stop taking your OI preventive medicine because you have had a sustained increase in CD4+ cell counts from being on effective anti-HIV therapies. If this were the reason, it would be unwise to stop taking your anti-HIV therapies as they are making your immune system stronger and able to ward off disease-causing organisms without the need of more drugs.

However, there could be other reasons why your doctor suggests that you go off certain medications, including concerns about drug interactions or side effects. Talk to your doctor to find out *why* she or he is encouraging you to stop taking any therapy.

The US Public Health Service has issued guidelines on when it may be safe to stop taking preventive OI therapies. For more information on these federal guidelines, please contact Project Inform's Hotline and ask for **PI PERSPECTIVE 28**.

## side effects

**I am considering stopping my anti-HIV therapies because of side effects. Does this sound reasonable? I have also heard that I might develop resistance to these therapies if I stop them. Is there anything I can do to reduce the risk of developing resistance? How long should I stop for and when I restart therapy should I use the same regimen or a different one?**

Dealing with drug side effects can be a real challenge. Most are treatable, either by switching a particular drug or by using ways to treat or manage the side effect. So the first response might best be exploring ways to treat or manage them, not to immediately stop your anti-HIV drugs.

It's important to remember that lots of people experience side effects for about a month or two after they start or switch to a new regimen. They usually decrease over time as your body adjusts to the drugs. However, if they continue for more than two months or get more severe over time, contact your doctor immediately.

Stopping anti-HIV therapies is one way to deal with serious side effects, but that decision is best made with your doctor. When you talk to your doctor, remember that there are potential concerns, including: a drop in CD4+ cell counts (in some people this can be quite dramatic); an increase in viral load; and a small but real possibility of developing resistance to one or more drugs in your regimen.

Resistance is not always well understood. The only time we're certain that someone won't develop resistance is when they're off treatment. There's some evi-

dence that going off treatment for awhile tends to reverse some of the resistance a person has already built up.

Does this mean that there's no chance of developing resistance from going off therapy? Not exactly. Even though there's little or no evidence of developing resistance after stopping therapy, there is still a *theoretical* concern—especially if you go on and off therapy several times.

Each time treatment is stopped and later restarted, it creates a brief period when there's an inadequate level of drug in the bloodstream. In theory, these periods are brief "windows of opportunity" for developing resistance.

To minimize this risk, it's important to not simply stop taking one drug in your regimen or to reduce the dose of a drug without guidance from your doctor. (For more information, read Project Inform's **RESISTANCE TESTS**).

If you choose to stop therapy, there is some slowly emerging information to help guide doing that more safely. Some experts suggest that people using nevirapine (Viramune) or efavirenz (Sustiva) stop those drugs two or three days before stopping other anti-HIV medications. This is because these two drugs remain in the blood much longer than other



drugs. Consequently, if you stop all the anti-HIV drugs at the same time, nevirapine or efavirenz will be found in the blood after the others have worn

off. This might increase the risk of developing resistance to either one. Ideally, the blood levels of all anti-HIV drugs should reach zero at about the same time.

Unfortunately, there is no good answer to how long someone should stop their anti-HIV drugs. We do know that after stopping therapy, it becomes even more important to closely monitor your CD4+ cell counts and viral load to help guide future decisions.

Finally, many factors need to be considered when restarting anti-HIV therapy. If the side effect(s) went away while you were off therapy, it's likely that one or more drugs caused the side effect(s). Restarting the same regimen may not be wise as those side effect(s) may reappear. This is not always the case, but switching to another regimen is probably preferable.

Another consideration is whether you could switch to a whole new regimen. If not, it's even more important to identify the drug causing the side effect and substitute it. It may also benefit you to take a resistance test before stopping the original regimen to help select a new one. Just remember, a resistance test can only be accurately done if you have a viral load above 1,000 copies/mL.

**I just found out I am seven weeks pregnant. Is it true that I shouldn't take any anti-HIV medications during the first trimester?**

# pregnancy

**t**he first trimester (14 weeks) of pregnancy is a time of great physical change for a woman and her developing baby. There are two main reasons why some doctors and women prefer to delay starting anti-HIV treatment during this time. One is the concern about side effects to the developing baby, and the second is the difficulty that starting therapy poses to a newly pregnant woman whose body is undergoing great change.



First, the beginning trimester is the time when the baby's organs, like the heart, lungs and brain, develop most rapidly and are especially fragile. The developing baby may be prone to harm from any drugs that the mother takes. So, some women may prefer to delay treatment until *after* the first trimester, when the baby's organ development is completed.

Some women taking anti-HIV drugs when they find out they're pregnant may switch or stop certain ones during the first trimester. Switching to those less likely to harm the baby is common. Stopping altogether, however, should be done with great

care as the drugs may help maintain the mother's health during this important time.

Second, many women experience morning sickness during the first trimester. These symptoms may worsen with therapy, making taking drugs as prescribed difficult. This may result in decreased drug levels in the blood, increasing the risk of drug resistance. So, delaying treatment may lessen these uncomfortable symptoms and prevent problems linked to poor adherence like developing drug resistance.

No woman should ever be denied treatment or forced to stop taking anti-HIV medications during the first trimester. Using therapy during this time should really depend on her own health needs and personal preferences. Understanding the risks and benefits associated with delaying, stopping or continuing medications during the first trimester is critical.

Lastly, anti-HIV medications help reduce mother-to-child HIV transmission. Anti-HIV therapies are only one part of a bigger picture of mother-to-child HIV prevention. Good prenatal care and stable support along with careful attention to the health and nutrition of the expectant mother are equally important.

For more information on HIV and pregnancy, call Project Inform's hotline and ask for **PREGNANCY AND HIV**.

## tried and true vs. brand spanking new

**Should I switch to a new (recently approved/available) anti-HIV drug right now? Are new anti-HIV drugs better than old ones?**

**a**s more anti-HIV drugs are developed, many wonder if they should switch to a newer drug. A new drug isn't necessarily better or worse than older ones. To decide if switching to a new drug is right for you, start by evaluating *new* the same way you evaluate *old*.

Collect and consider the available information about potency, drug interactions, reported side effects and dosing schedule. Remember that while a new drug often sounds good—especially amid the hype of marketing campaigns—it may not be the one for you. Think strategically about your future options and plan for the long-term before you switch.

Perhaps most importantly, think about your reasons for changing. If you're currently doing well and have minimal side effects, changing might not be wise. You would be stepping off into the unknown, while abandoning something that's working well

for you. On the other hand, if you're experiencing some level of drug failure, adherence problems or serious side effects, it would be wise to consider a change.

That said, a new drug may (or not) be more potent than the current drugs—maybe even against resistant virus. If it is, this is good news for those who have taken many anti-HIV drugs and are "treatment experienced." A new drug might be easier to take—with once a day dosing, for example. This can lead to improved adherence. Also, it could claim fewer or more tolerable side effects overall, making it an attractive option for those struggling with side effects.

There is sometimes a psychological boost from taking something new. Because few people have taken the drug, there's little negative news about it, which makes people feel good. Feeling good and hopeful about treatment can lead to better adherence and health in general.

On the other hand, a new drug has often only been used by a small number of people for a limited time. This means that some of the information about the drug may not be apparent until more people, like you, use it. We have less information about a new drug than almost any older drug. And six months or a year from now, we will know more about it than we do today.

Also, doctors generally have less experience with a new drug, and so they aren't used to recognizing its potential side effects. New can also mean that side effects aren't well characterized yet. This might worsen quality of life and interfere with the ability to adhere. However, this is not unique to a new drug. It's a risk associated with switching in general.

Most people, rather than jumping on the new drug bandwagon, will wait until more doctors and patients have used the drug and experienced and managed side effects, so that when they are ready to make a switch there's more information to consider. Ultimately, the key to switching to a new drug or an older one is *strategy*: don't switch without a reason for doing so, and if you do, don't plan only for the short-term but for a long and healthy treatment future.

## FDA APPROVES NEW 3-IN-1 DRUG TRIZIVIR

The Food and Drug Administration (FDA) has approved Trizivir, a three-drug combination tablet that includes standard doses of abacavir (Ziagen), 3TC (Epivir) and AZT (Retrovir) in a single pill. The new pill allows for easier dosing of three-drug therapy: only one pill twice daily.

In people who have not taken anti-HIV therapy before, this combination has shown short-term benefit comparable to that of regimens with protease inhibitors. With



the added benefit of many fewer pills, this should also improve adherence.

However, results from one study showed that people with a viral load over 100,000 copies/mL did not respond as well to abacavir/3TC/AZT as those who used a three-drug regimen including a protease inhibitor. This difference was not seen in a second similar study.

The usual precautions about allergic reactions (called *hypersensitivity*) to abacavir also need to be considered for Trizivir. People who weigh less than 100 pounds should talk to their doctors about safety concerns associated with weight before taking the drug.

## FDA ISSUES WARNING FOR NEW DRUG LOPINAVIR

Last September, the FDA approved the new protease inhibitor Kaletra (formerly ABT-378). The drug contains lopinavir plus a small amount of ritonavir (Norvir), which helps boost lopinavir levels in the blood.

A warning has been issued about the possibility of developing *pancreatitis* (inflammation of the pancreas) while on this drug. Less than 1% of the people in studies including of lopinavir developed pancreatitis.

It's not possible to definitively say that people developed pancreatitis from taking lopinavir, as some were also taking other drugs known to cause pancreatitis like pentamidine, ddI (didanosine, Videx) and d4T (stavudine, Zerit). Additionally, some volunteers had very high triglyceride levels, which can result in pancreatitis. Nevertheless, people on lopinavir should carefully check their amylase levels (a marker for pancreatitis) and work with their doctors to identify early warning symptoms.

## CDC REPORTS HPV AS MOST COMMON STD

The Centers for Disease Control and Prevention recently reported that nearly 18% of women and 8% of men in the U.S. carry the human papillomavirus (HPV). The virus causes more than

95% of cases of cervical cancer, and the HPV-16 strain causes half of them. According to the research, the highest rates of HPV-16 infection were found among African American women aged 20 to 29, the same group of women hardest hit by HIV infection.



About 2 in 10 women in the US have HPV

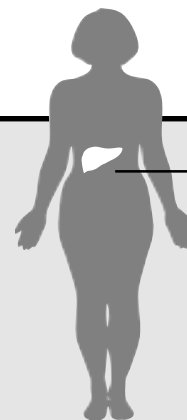
HPV-related symptoms include genital warts and early stage anal and cervical dysplasia. These symptoms can be treated, and regular monitoring is important to catch them early.

While some people may not choose to treat anal/genital warts because of high recurrence rates, monitoring and treating the condition is critical should it turn pre-cancerous. Left untreated, these conditions can worsen, especially in people with a weak immune system. Thus, this study is an important reminder for the importance of regular cervical Pap smears that can detect HPV-related dysplasia—leading to its treatment and lowering of anal and cervical cancer as appropriate.

Remember, positive women should get a Pap test every six months, and more often if something is wrong. Read Project Inform's **GYN CONDITIONS** for more details.

## New Nevirapine Warning

Nevirapine (Viramune) is known to cause hypersensitivity in up to 25% of people taking the drug. In less than 1%, these reactions are severe. Severe liver damage has also been reported in people taking nevirapine. New recommendations enforce the need for careful monitoring when taking nevirapine—especially during the first 12 weeks of use—when severe side effects, if they are going to occur, are most likely.



### Liver Side Effects

**COMMON**  
tiredness  
loss of appetite  
nausea  
high liver enzyme levels

**SEVERE**  
jaundice  
swollen liver

## EXPANDED ACCESS PROGRAM BEGINS FOR TENOFOVIR

Gilead Sciences, the developers of a new nucleotide analogue, tenofovir (PMPA), started a small expanded access program in January. The most important use of this drug, for now, will probably be in people who have developed resistance to several of the NRTI drugs, like d4T (Zerit) and AZT (Retrovir), and need something new to shore up their combination therapy. It is less clear whether the drug will compensate for protease inhibitor failure. The initial program will begin small and expand during 2001 as drug supplies increase.

### To qualify, people must have all of the following:

- Over 10,000 copies HIV RNA and CD4+ cell counts below 100 or CD4+ cell counts below 200 and an opportunistic infection within the past three months;
- Intolerance to and/or viral load increases to at least two protease inhibitors or one protease inhibitor and one NNRTI (for a list of the names and types of anti-HIV drugs, call Project Inform's Hotline); and
- Unable to construct a viable drug combination without tenofovir.

To register patients in the program, physicians should call 1-800-445-3235. As more drug supplies become available, the criteria to qualify will change.



## public policy roundup

Election year politics kept Congress from completing a lot of work, but there was still quite a bit of activity on HIV/AIDS issues in 2000. Below is a brief summary of this year's successes, missed opportunities, and some challenges we in 2001.

### Successes

The biggest victory for people living with HIV/AIDS was the *reauthorization* of the Ryan White CARE Act. The CARE Act funds HIV/AIDS care, treatment and support services nationwide, such as the AIDS Drug Assistance Program (ADAP), primary care, case management, food delivery and dental programs.

The CARE Act was going to expire on September 30, 2000, and needed to be *reauthorized* (or renewed) by Congress and President Clinton for another five years.

After a slow start, Congress was able to pass a bill, which was signed by the President in October. While not perfect, the CARE Act is secure for another five years. This victory is the result of broad support by Democrats and Republicans in Congress and tremendous efforts by AIDS advocates nationwide.

Many advocates spent time this summer fighting a proposal to create financial incentives within the CARE Act for states to pass laws requiring HIV testing of pregnant women and newborns. A coalition of organizations—including Project Inform, National Minority AIDS Council, AIDS Foundation of Chicago, AIDS Legal Referral Panel, LAMBDA Legal Defense and Education Fund and the HIV Law Project of New York—came together to fight this proposal and offer reasonable alternatives. The result was a compromise that allows a couple of states with “the most significant demonstrated success” in reducing mother-to-child HIV transmission to apply for special funds in the CARE Act. States with mandatory newborn testing programs may apply for these funds as well.

### Missed Opportunities

Unfortunately, Congress missed the opportunity to pass laws that

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review of 2000



You can play a key role in these issues by joining Project Inform's **TREATMENT ACTION NETWORK**. TAN members respond to Action Alerts and communicate with their elected officials about legislative and funding issues that affect them and people they care about. Lawmakers need to know how their actions and votes affect the people they represent. We provide the information and assistance you need to prepare your message to your legislators. If you would like to join TAN and make your voice heard on any of these issues, call Project Inform's toll-free hotline at 1-800-822-7422 and ask for a TAN membership form, or email your name and contact information to [tan@projectinform.org](mailto:tan@projectinform.org). Your help is needed more than ever!

# public policy roundup



would have a positive impact on many people living with HIV/AIDS.

The Patients' Bill of Rights continues to be stalled in Congress. This bill would provide protections for individuals in a managed care system, and help insure better access to healthcare and treatment. Even though a compromise bill was created that was acceptable to many Republicans and Democrats—and supported by President Clinton—it still wasn't passed before the end of 2000's Congressional session. Given the new President and Administration, pressure may be necessary to keep this bill intact and a priority for the new Congress.

There was also a last-minute attempt to pass the "Early Treatment for HIV Act" at the end of the year. This bill would have given states the option to provide Medicaid coverage for uninsured, low-income people living with HIV. Currently, most HIV-positive people are not eligible for Medicaid until they receive an AIDS diagnosis. This bill would allow people to start receiving healthcare and treatment services before becoming ill. The bill did not make it through Congress before the end of the year, and it remains a priority for advocates.

### Upcoming Challenges

The new year presents some serious challenges and opportunities. For the

first time in eight years, we have a new President and Administration. There is also a fairly dramatic change in the makeup of Congress, especially in the Senate which is now evenly split between parties. It is unknown what specific challenges lie ahead as a result of these changes. We must work to make sure the government's response to HIV/AIDS remains a priority for the new Administration and Congress.

Specifically, it is clear that we will likely have to continue to fight on the issue of HIV testing of pregnant women and newborns. The Centers for Disease Control and Prevention (CDC) will soon release new guidelines on the issue. We know from the CDC's draft that the guidelines will contain some good provisions and attempt to increase the availability of HIV testing for pregnant women.

However, the general trend of the guidelines weakens a pregnant woman's right to informed consent for HIV testing and adequate pre-test counseling. This right means getting the complete information needed in order to make an informed choice on whether or not to test for HIV. While many organizations submitted comments on the draft, it is possible that the final guidelines will cause some legislators in Congress and state legislatures to pass laws limiting a pregnant woman's rights.

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