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tagline

NEWS ON THE FIGHT FOR BETTER TREATMENT, A VACCINE, AND A CURE FOR AIDS

Inflammatory Debate over When to Start

BY RICHARD JEFFERYS

The CD4 cell count at which combination antiretroviral therapy should be started is a central, unresolved issue in the care of HIV-1–infected patients.

—When To Start Consortium, "Timing of Initiation of Antiretroviral Therapy in AIDS-free HIV-1 infected Patients: A Collaborative Analysis of 18 HIV Cohort Studies"

Ever since the first anti-HIV drug was approved for prescription in 1987, there has been debate and controversy regarding when an HIV-positive person should start antiretroviral therapy (ART). Up until the mid-1990s, the question revolved around maximizing the limited benefits of treatment with one or two nucleoside analogue reverse transcriptase inhibitors (NRTIs)—such as AZT, ddI, ddC, d4T, 3TC, and the like—in temporarily staving off progression to AIDS. The advent of combination ART capable of prolonged—and potentially lifelong—suppression of HIV replication altered the landscape drastically, and now the focus is on the risks and benefits of earlier versus later treatment over decades. But for hundreds of thousands of HIV-positive people diagnosed at higher CD4 counts, this life-altering treatment decision has been fraught with uncertainty due to lack of the most reliable, rigorous evidence—that derived from well-designed, controlled, randomized clinical trials.

In the United States, the task of synthesizing the available evidence and making recommendations on how to use ART falls to a panel of experts who issue regularly updated guidelines under the aegis of the U.S. Department of Health and Human Services (DHHS). In December 2009 the DHHS guidelines panel revised its recommendation on when to start ART, raising the threshold from less than 350 CD4 cells to less than 500. The panel was split over the strength of this specific recommendation, with 55% endorsing it strongly and 45% moderately. Half of the panel also went even further, offering a moderate recommendation to start

Continued on page 2

A New Start for an Old Movement

The Making of the HIV Research Catalyst Forum

BY LEI CHOU AND COCO JERVIS

After a five-year hiatus, NATAF (North American AIDS Treatment Action Forum), a community conference focused on HIV treatment and prevention research has re-emerged onto the national scene. Renamed the HIV Research Catalyst Forum and organized by TAG and many allied agencies, the 2010 HIV Research Catalyst Forum took place in April in Baltimore.

In 1995, the original NATAF met during a heady time in AIDS research activism. The first protease inhibitor was nearing FDA approval, and combination therapy was about to fundamentally change the course of the HIV epidemic. Treatment activists were witnessing hard won victories, manifest in their lives and the lives of people around them. The possibility of eradication was on everyone's lips, a preventive vaccine seemingly just around the corner. The NATAF conference organizers took on the challenge of translating these research advances to communities around the country, through

Continued on page 5

WHAT'S INSIDE

Inflammatory Debate, continued from page 1

ART at any CD4 level, with the other half considering this approach optional. (The revised guidelines are available online at http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf). This change to the DHHS guidelines has generated controversy for a number of reasons. Most prominently, there is ongoing debate over the quality of the scientific evidence available to address the effect of starting ART at different CD4 cell count thresholds. The gold standard for evidence is the randomized controlled trial (RCT), in which individuals with very similar characteristics are randomly assigned to different interventions or strategies. In the absence of results from RCTs, data obtained from large cohorts of people with HIV in medical care is the most common secondary source of evidence. However, cohort studies are notoriously subject to a problem called *confounding bias*; a *confounder* is a factor associated with the outcome of interest that the study fails to capture. As an example, it could be that a member of a cohort who starts ART early has other factors associated with better health—such as access to private insurance and lower copays, or greater health-seeking behavior—and these factors could be more important to the study outcome than ART. Conversely, a cohort member who starts ART late may have risk factors for illness that the study fails to capture.

There is virtually no evidence from RCTs of when to start ART among ART-naive individuals starting treatment with CD4 counts over 350/mm^3. Most of the evidence cited in support of the new DHHS recommendations is derived not from RCTs but from two published meta-analyses of data from multiple large cohort studies, with additional support from smaller studies of HIV pathogenesis, particularly those describing harmful long-term effects of HIV-induced inflammation. A community sign-on letter addressed to the DHHS guidelines panel has expressed concern that the change could inadvertently make it more difficult to complete a critically important RCT that is being conducted by the INSIGHT network expressly to address the when-to-start question; this trial (known as START) is in a pilot phase and aims to compare initiation of ART at a CD4 cell count over 500 to deferral to a count of less than 350 cells (http://i-base.info/files/2010/05/CABStatementOnSTART.pdf).

Concerns about prevention have brought an additional wrinkle: for the first time, the DHHS guidelines note that suppression of viral load by ART is associated with a greatly reduced risk of transmitting HIV. This has caused some people to fear that the push to recommend earlier treatment is being made to prevent new infections. Despite the lack of conclusive evidence for clinical benefit to the individuals who will be initiating treatment for their own HIV infection.

This is the second in *TAGline*'s 2010 coverage of ongoing changes in the standard of care for HIV treatment, following Mark Harrington's "World Health Organization HIV Treatment Guidelines Evolve," a review of the new World Health Organization adult and adolescent antiretroviral treatment guidelines. www.treatmentactiongroup.org/publication.aspx?id=3578

Sorting though the tangle of issues now caught up in the when-to-start question is not easy. As a baseline, there is widespread consensus that ART should be initiated when CD4 counts drop below 350, and this recommendation is supported by data from cohort studies and results from an RCT that were presented in 2009. The study, called CIPRA HT 001, enrolled 816 individuals in Haiti and compared starting ART with a CD4 count between 200 and 350 to deferring until the CD4 count fell below 200. An interim analysis revealed that deferral was associated with a significantly increased risk of illness and death and the differences were so stark (23 deaths in the deferred group versus 6 in the immediate group) that the trial was stopped by the Data Safety Monitoring Board. At CD4 levels above 350, uncertainty intrudes. The only randomized data available are derived from a subset of participants in the Strategies for the Management of Antiretroviral therapy (SMART) trial, which was an evaluation of intermittent versus continuous ART. Two hundred and forty-nine people (out of a total of 5,472 participants) entered the study with >350 CD4 cells, having never taken ART. Of these, 131 were randomized to start ART immediately while 118 deferred until CD4 counts were lower than 250. Over an average follow-up of 18 months, there were seven cases of serious illness or death among people who deferred ART compared to two among people who started immediately. There was only one death, which occurred in the deferral group and was caused by cardiovascular disease. Because there were too few people in this subset for the results to reach statistical significance, the researchers conducted analyses that included individuals who had taken ART in the past but had been off for more than six months when they enrolled in SMART. With this group included, the difference in illnesses and deaths between the deferred and immediate groups became statistically signifcant, increasing the totals to 21 versus 6 events. The result was also significant if only those participants who had been off ART for at least a year were considered. However, there were some modest differences between participants who had never taken ART and the added group of those who had interrupted treatment. Members of the latter group were three years older on average and were more likely to have certain additional risk factors for illness (such as smoking) despite comparable CD4 cell counts (both current and the lowest levels ever reached). these factors may have exacerbated the risks associated with deferring ART. The authors of the paper describing these subset analyses from SMART (which was published in the *Journal of Infectious Diseases* in 2008) take pains to stress that the results are exploratory and need to be confirmed by an RCT.

The main evidence cited in support of the new DHHS recommendation to start at >350 CD4 cells comes from a large cohort study called NA-ACCORD (a "cohort of cohorts" that collates data from a number of smaller cohorts). In an influential paper published in the *New England Journal of*

Inflammatory Debate, continued from page 2

Medicine in 2009, researchers reported that cohort members who started ART at either >350 CD4 cells or >500 cells faced a significantly lower risk of death compared to those who deferred. It's important to stress that, as with the SMART analysis described previously, the risk of death during follow-up was very low even among those who deferred. What the researchers emphasize is that the relative risk was significantly different, and this difference is expressed in terms that can easily mislead; for example, waiting until a CD4 count was below 500 was said to increase risk 94% compared to starting at above 500, and some people mistakenly interpreted this as suggesting that delaying ART meant death was a near certainty. However, in this context a 94% increase means roughly a doubling in risk, which for those with a CD4 count above 500 was relatively low (1.3 deaths per 100 person years, or approximately 13 deaths out of every 1,000 people followed for a year).

The statistical approach used by the researchers did not allow an absolute death rate to be calculated for either of the deferral groups in the study. This approach is called *inverse probability weighting* and it is designed to address confounding factors that can affect comparisons of different treatment regimes using cohort data. Under this method, individuals are censored from the analysis if they deviate from the treatment regime being studied, and statistical modeling replaces the censored data with a "pseudoperson" for whom the outcome is calculated based on probabilities derived—by means that are not clear—from the same cohort. The confusing and opaque nature of this analytical method is one of the main concerns about the NA-ACCORD paper. The use of the inverse probability weighting technique by NA-ACCORD researchers has been questioned by Miguel Hernán and James Robins, the statisticians who originally developed it. Hernán has submitted a reanalysis of the same data for publication, but the article has yet to appear, and the extent to which it differs from the original results is not yet known. The other major cohort study cited in the DHHS guidelines is the Antiretroviral Cohort Collaboration (ART-CC). The ART-CC's analysis of 18 different cohorts supports the conclusions of the NA-ACCORD regarding starting at 350 CD4 cells but is equivocal at higher thresholds, prompting some debate between the two sets of researchers. Specifically, the ART-CC reported a reduced risk of reaching a composite endpoint of AIDS or death associated with starting between 350 and 450 CD4 cells compared to deferring to 250–350 CD4 cells, but when mortality was evaluated alone there was not a statistically significant difference. Furthermore, there were no significant differences associated with starting at CD4 thresholds over 450.

Without information on all potential confounders, as well as information on any negative aspects of HAART [highly active antiretroviral therapy] *when initiated at higher CD4 cell counts, the benefit-to-risk ratio for early use of antiretroviral therapy remains unknown and we must await data from RCTs* [randomized clinical trials] *before final conclusions can be reached.*

—Caroline Sabin, "Cohort Studies: To What Extent Can They Inform Treatment Guidelines?"

In addition to the cohort data, the guidelines articulate an important concern driving the shift to earlier ART: "later therapy may not repair damage associated with viral replication during early stages of infection." The SMART trial (which evaluated whether ART could be used intermittently to keep CD4 T-cell counts out of the danger zone for opportunistic infections, rather than continuously) brought risks associated with viral replication and the attendant inflammatory response to the fore in 2006. The results were unequivocal, showing that intermittent ART was associated with a doubling of the risk of serious illness and death when compared to continuous ART.

Although absolute risk of illness and death was relatively low in both arms (around 3% and 1.5%, respectively), the difference was highly statistically significant. Differences in morbidity and mortality between the arms were also seen at all CD4 strata and not just the lowest. Most of the illnesses that occurred were not AIDS-defining events based on Centers for Disease Control and Prevention criteria but cardiovascular, kidney, and liver disease and cancers. The researchers who conducted SMART also collaborated with specialists from outside of the HIV research field to look for factors linked to illness and mortality in the trial. One such expert, Lewis Kuller, led a study that showed that biomarkers of inflammation (specifically the cytokine IL-6 and a marker linked to blood coagulation, D-dimer) were strongly linked to mortality in SMART, with statistical associations that dwarfed those Kuller had previously documented in non-HIV-infected elderly people. Other common risk factors were also predictive of mortality in SMART, including age, smoking, prior cardiovascular disease, co-infection with hepatitis B or C and baseline CD4 cell count, but the elevated inflammation associated with treatment interruption increased risk independently of any of these baseline variables. Important for the guidelines panel is that studies have found that the level of inflammation that persists after starting ART is associated with the CD4 cell count at starting; the lower the count, the higher the level of persistent inflammation.

Another related issue is the ongoing accumulation of worn-out or *senescent* T cells that accompanies uncontrolled HIV replication. Senescence is seen in both CD4 and CD8 T cells but is more prominent for CD8s, and research outside of the HIV field has shown that higher numbers of these cells are associated with illness, frailty, and earlier mortality among the very elderly. Senescent T cells are characterized by the loss of an important cell surface molecule called CD28, an inability to proliferate (copy themselves) in response to stimulation, production of high levels of proinflammatory cytokines, and a stubborn resistance to cell death (apoptosis). Recent studies in HIV have found that elevated numbers of senescent CD8 T cells are associated with more rapid disease progression and with inflammatory damage to blood vessels that presages cardiovascular disease. Relevant to the issue of when to start ART, it is as yet unclear whether there is much decline in numbers

Inflammatory Debate, continued from page 3

of senescent T cells after viral load is suppressed, suggesting that it may be better to intervene earlier in order to prevent their accumulation. The literature from research into the role of senescent T cells in aging indicates that they persist once present, raising the worry that if they are allowed to accumulate in a person with HIV they could be a harbinger of more rapid aging.

On the other side of the equation from the potential risks of deferring ART are the risks associated with the drugs themselves. Although the DHHS guidelines cite evidence that more recently marketed antiretrovirals have improved safety profiles when compared to those of earlier generations, they also acknowledge that long-term data are lacking. Somewhat reassuringly, neither the NA-ACCORD or ART-CC studies described earlier found evidence of harm associated with starting at high CD4 cell thresholds. However, as Caroline Sabin wrote in 2009, the only way to definitively characterize the risks and benefits of earlier treatment is via a randomized clinical trial.

Since the December 2009 guidelines update, conversations about when to start ART are likely happening in doctors' offices around the country. Given the complexity of the available data and the uncertainty over the risk versus the benefit of starting early, making this treatment decision has not become any easier. As START trial sites open up around the country, enrolling in the study might be an option to consider. Besides contributing to the body of knowledge on HIV, being randomized to either the treatment or deferred arm of the study may be a way to turn a perplexing question into answers that will benefit countless people with HIV in the United States and around the globe.

For more information about the START trial, go to: http://insight.ccbr.umn.edu/start/. To find a trial site near you, visit the START website at http://www.clinicaltrials.gov/ct2/show/study/.

The online version of this article has a complete list of hyperlinked references.

History and Global Importance

TAG has been advocating for an RCT addressing when to start ART for the past 18 years. The AIDS Clinical Trials Group (ACTG) once mulled such a study and even got as fas as assigning the protocol a name (Strategic Timing of ART), but the plan was eventually deemed "overly ambitious" and abandoned in 1997. In a speech given at the 1999 AIDS Update Conference in San Francisco, TAG's Mark Harrington described the failure to conduct an appropriate RCT as an "unacceptable collective evasion of responsibility" (*TAGline* 6, no. 4, June 1999)

An RCT is also imperative from the perspective of global AIDS treatment guidelines. At a time of recession and pushback against treatment rollout in the developing world, it is vital that WHO recommendations be based on the highest quality of evidence possible.

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Can More People Be Put on ART Without Increased Cost?

With no end to the global funding retreat in sight, new strategies are required to change the way we provide treatment to the world's 33 million people infected with HIV.

On June 7-10, the Clinton Health Access Initiative (CHAI) hosted a conference, *Opportunities to reduce the cost of anti-retroviral (ARV) treatment*, to explore opportunities to significantly lower the costs of anti-retroviral therapy (ART). Dose finding during drug development often maximizes tolerability but sometimes fails to explore minimally effective dosing. The earliest example of dose adjustment was AZT (zidovudine), which was initially tested at much higher doses (1500 mg daily compared with today's dose of 600 mg daily).[1] Back in 1990, activists applied pressure to speed up the FDA's approval of AZT's use at the lower, safer, equally effective dose.[2,3]

With clinicians, pharmacologists, chemists, researchers, regulatory experts, and community advocates in attendance, discussions included reformulation, dosage optimization and manufacturing along with attendant issues of regulatory pathways and ethical considerations for optimized ARV regimens. If dose optimization and reformulations are proven to be safe, efficacious and significantly cheaper, many more people could be enrolled on first-line ART using existing funding flows—in effect, more people on treatment for the same drug costs.

A significant step toward dose optimization is in motion with the Evaluation of Novel Concepts in Optimization of antiRetroviral Efficacy (ENCORE) study to evaluate reduced doses of efavirenz which is being conducted at the University of New South Wales, Australia. The study will be conducted through an international research network with sites in high-, middle- and low-income settings. Data are expected by mid-2013. If successful, this could set the stage for cheaper regimens, new fixed dose combinations and most importantly, more people on ART. ●

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3. Gina Kolata, "Lag in Approving Low AZT Doses is Assailed," The New York Times, 27 December 1989.

A New Start, continued from page 1

treatment education and advocating for public policies to ensure access. Looking back, it must have been hard to imagine that this meeting would still be needed fifteen years later.

In the years since the first NATAF, the AIDS epidemic has marched on relentlessly. Researchers are not getting closer to a cure or a vaccine. Transmission rates defied our best behavioral interventions. Available drugs were increasingly seen as "good enough," and life-long therapy an acceptable reality. Treatment uptake slumped under the weight of rising drug costs and political indifference. Long-time survivors, including many leading activists, started dying from non-AIDS defining co-morbidities.

While these challenges multiplied in number and complexity, a parallel revolution in how people access and use information, define their communities, and organize advocacy took place. Those crowded weeknight meetings with xeroxed journal articles and face-to-face debate that gave birth to AIDS research activism are gone—along with the sense of urgency that brought people to those weekly meetings and demonstrations. We have lost the camaraderie, the mentoring, and the shared optimism at the core of research activism.

In planning for this year's HIV Research Catalyst Forum, TAG and our allies set out to reignite that sense of optimism, while recognizing the new possibilities and challenges of grassroots organizing in the year 2010.

Today there are well-established national virtual networks of advocates working on treatment and prevention research, and highly professionalized organizations with well defined missions and staff capacity. There is also a palpable void created by NATAF's five year absence—a focus on the importance of community driven research activism. The goal of the Catalyst Forum was to replicate some of the key components critical in the success of the original AIDS activist movement: transfer of knowledge and experience to engage new activists; provision of support and guidance in navigating the complex research landscape; and formation of a cohesive sense of community and the power it bestowed.

With initial funding provided by the Office of AIDS Research of the National Institutes of Health, and additional support from non-profit organizations and industry, an online scholarship form was launched to assess the interest for a research focused meeting in the community, as well as to gauge the level of awareness in treatment and prevention research issues. Any doubts about interest for this meeting was put to rest by the nearly 900 applications that came in from around the country. A close look at the applications revealed much passion and commitment in staying the fight against AIDS, but simultaneously a disconcerting lack of understanding and awareness on the important role research plays in that fight. Whether this is due to NATAF's absence, the gradual erosion of the value of community activists limited to personalities and individual testimonials, or some other factor, it was clear that an issue-oriented and skills-based activist movement driven by community perspectives should be an important outcome for the conference.

A program committee composed of leading activists was charged to tackle these challenging goals. The resulting program consisted of various session formats to engage attendees through a rigorous process of information gathering, skills building, critical analysis, problem solving, and strategy development. With a faculty to participant ratio of 1:3, a wide spectrum of cutting edge prevention and treatment research challenges were presented and studied. A shared desire by the planners to avoid hosting another conference where the energy and momentum dissipates after attendees return home, both formal and informal networking opportunities were sprinkled throughout the proceedings. The four-day meeting ended with recruitment stations for advocacy networks to absorb the 250 attendees into ongoing work, and a rousing closing plenary emphasizing the importance of community research advocacy from a researcher's perspective was powerfully delivered by Drs. Vicki Cargill and Bob Fullilove.

Recognizing the unique advantages provided by the digital environment for organizing the research advocacy community, including access to the target audience, efficient information delivery and collection mechanisms, and networking opportunities, the conference website and blog was positioned at the nexus of various organizing activities. HIVResearchCatalystForum.org became the home base, where scholarship applications and post-conference evaluations were conducted, presentation slides and web casts were posted, advocacy networks and research resources were linked, and advocacy sign-on letters were hosted. Daily feedback from attendees on their experiences via the conference blog gave people unable to attend a taste of the proceedings.

A blog is not the same as sitting in an old ACT UP meeting slogging through research articles—but if the overwhelmingly positive participant feedback is any indication, the first HIV Research Catalyst Forum has reinvigorated some of the passion and motivation at the heart of this movement. For a more detailed report on the Catalyst Forum and its outcomes, please visit: www.hivresearchcatalystforum.org/report.

HIV Research Catalyst Forum

Matt Sharp discusses the quest for a cure.

What U.S. Health Care Reform Means for People with HIV

Slow implementation for needed changes

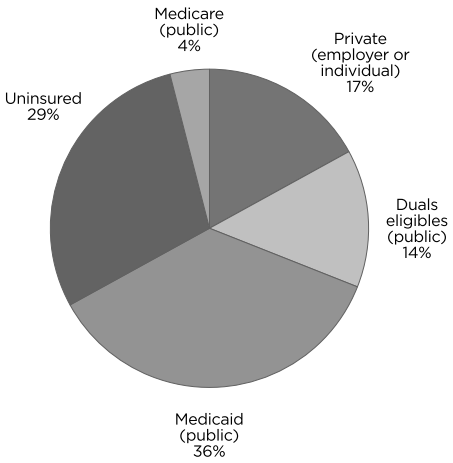
BY COCO JERVIS AND SUE PEREZ

After a century of failed efforts, decades of debate, and months of partisan rancor, this past March, Congress finally passed the *Patient Protection and Affordable Care Act of 2010* and *Health Care and Education Reconciliation Act*. The 2010 health care reform overhaul package is the most comprehensive national health care legislation in the history of the United States and the most ambitious expansion of health care since the creation of Medicare and Medicaid in 1965. While this historic law fell short of a public option with universal coverage that the HIV community, and most of those who believe that health care is a basic human right, called for, it will provide coverage for an estimated 32 million uninsured Americans when fully implemented after 2014.

The new law does not radically change HIV care at the outset. In some ways, people with HIV have had more flexible and comprehensive treatment options than many other Americans, at least since the passage of the Ryan White CARE Act in 1990—despite frequent abuses of drug price increases by industry and equally outrageous and frequent interruptions of treatment manifested by egregious and cruel waiting lists at the state level—which at last count topped over 1,800 people—for antiretroviral treatment.

If the changes mandated in health care reform are implemented and given time to evolve, the U.S. health care system will undoubtedly improve, but these changes will not be achieved overnight and for people with chronic diseases or those who currently lack adequate health coverage, progress may seem agonizingly slow—nor will the law fix all the problems inherent in the fragmented U.S. health care landscape. The speed and scope of implementation of health care reform depends on a labyrinthine system of interacting factors and players at the federal, state, and private sector levels, and will also depend on how adeptly the Obama administration can push through needed regulatory frameworks before needing to respond to the coming election cycles. Many people with HIV were unable to meed Medicaid's stringent eligibility requirements-not only the low income threshold-but the requirement to be medically disabled.

Snapshot of health care coverage for the estimated 1.1 million people with HIV in the U.S.[1]



Key changes and their impact on HIV treatment and care

1. Impact on low-income people who use Ryan White clinics and the AIDS Drug Assistance Program (ADAP)

When the first anti-HIV drug, AZT (Retrovir, zidovudine), was approved in 1987, there was outrage because of its then unprecedented cost of $10,000 per year, much more than most people with AIDS could afford. Thus, a major reason behind the original push for the Ryan White CARE Act was the inadequacy of Medicaid, the nation's primary healthcare program for people with low income. Many people with HIV were unable to meet Medicaid's stringent eligibility requirements—not only the low income threshold—but the requirement to be medically disabled.

NOW: The new law changes both of these enrollment barriers through the expansion of Medicaid coverage to low income individuals and families. As such, the annual income limit will be raised from $8,014 to $14,404 for an individual, but more significantly, people will no longer have to become disabled by disease to qualify. This also means much more comprehensive coverage, including hospitalization and a full drug formulary, than what Ryan White offers. Since the majority of people who rely on Ryan White-funded clinics and ADAP fall within the new income limit, this Medicaid expansion will stabilize and improve healthcare for most low income people with HIV who do not have private insurance. By 2014, when this component of the reform law is fully implemented, many people with HIV will no longer have to face the horror of ADAP waiting lists again. Ryan White and ADAP will finally become the programs they were meant to be–the emergency provider of last resort.

2. Impact on people who were denied coverage by private insurance

One of the basic concepts behind health insurance is the distribution of risk between the young and the old, the sick and the healthy. Many people with HIV who can afford to purchase private health insurance have been unable to do so due to the pre-existing condition of their HIV infection.

NOW: This practice will be prohibited for private insurers under the new reform law starting in 2014. However as a stop-gap measure between now and 2014 the Department of Health and Human Services (DHHS) will administer a temporary national high-risk insurance pool. To qualify, individuals must be uninsured for at least six months or must have been denied a policy because of a pre-existing condition. Out-of-pocket expenses will be capped for

Health Care Reform, continued from page 6

individuals at $5,950 per year. The combination of private insurance, state-regulated insurance "exchanges" and federal mandates are supposed to provide near-universal coverage by 2014, including a mandate for all U.S. citizens to purchase health insurance. The rationale of the state exchanges is to allow market forces to keep costs affordable while allowing people to choose the amount of coverage best suited to their needs. It is unclear how or even whether this will work in practice, as there is a danger that premiums will simply be too expensive. Federal subsidies will be provided for people making less than $43,320 a year, with possible exemptions for certain categories of people including those with yet undefined "financial hardships". The difficult details of how this will actually work remain unclear.

3. Impact on people receiving Medicare who are stuck in the $3,600 Medicare drug coverage donut hole

For many people with Medicare drug coverage, the infamous "donut hole" created under the Part D expansion during the Bush Administration has caused immense frustration. To put it simply, people in the program pay the first $300 in prescription drug out-of-pocket expenses in addition to their monthly premiums. Plans then usually cover up to $2,830 per year in prescription drug costs at which point individuals must then fork over an additional $3,610 "donut hole" before they can take full advantage of the program.

NOW: Over the next ten years, Medicare Part D provisions will incrementally expand to eventually fill the donut hole. For people with HIV, starting in 2011, all brand name drugs (including most HIV medications) will be offered at a 50% discount, plus a $250 federal rebate will be paid directly to individuals this year. Currently, ADAP has been covering people stuck in the donut hole through a wrap-around measure, but since ADAP funds cannot be used to fill the hole, this means most people end up getting their medication through ADAP instead. Starting next year, ADAP can help fill the hole, and people will revert back to getting their medications through Medicare, paying just 5% of the drug cost, and freeing up much needed ADAP dollars for others without any drug coverage.

Looking Forward

Despite the stabilizing progress the 2010 health care reform law will make toward improving health care for people living with HIV, the future is certain to bring continued challenges in health care access, quality, and cost. Although many of the most important reforms do not go into effect until 2014, the protracted implementation will likely provide sufficient time for states to transition people from Ryan White-funded programs to newly created entities and structures. There are some glaring problems, such as the exclusion of undocumented immigrants from participation, the lack of cost control on drugs and insurance premiums, and the failure to address physician reimbursement to further stabilize the system. However, the health reform law is a giant leap forward. It will take much work on the part of people with HIV and their advocates to help ensure that the promise of health care reform is kept for people with HIV and everyone else in the United States.

For more information on health care reform, please visit the following websites:

• HealthReform.gov (Obama Administration website on new law)—http://www.healthreform.gov

• Treatment Access Expansion Project (Analysis of HIV-related provisions)—http://www.taepusa.org

• Kaiser Family Foundation (summaries and implementation timeline)—http://healthreform.kff.org

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AIDS Drug Assistance Program Crisis Explodes—Over 1,800 people with HIV now on Waiting Lists for Treatment Nationwide

In the midst of increasing state health budget cuts and service eliminations, people living with HIV/AIDS and advocates are gravely concerned about increasing AIDS drug assistance program (ADAP) waiting lists, formulary reductions, and eligibility constrictions throughout the country. ADAPs provide lifesaving HIV treatment to low income, uninsured, and under-insured people living with HIV/AIDS throughout the United States.

In the last 12 months over 1,800 people have been put on waiting lists for treatment in Florida, Illinois, Hawaii, Idaho, Iowa, Kentucky, Montana, North Carolina, South Carolina, South Dakota, Utah and Wyoming—with more states certain to follow. People are getting sicker and experiencing treatment interruptions as a result of the lack of access to HIV medications—with no end in sight.

The HIV advocacy community has reached a breaking point—now is the time to take action.

What You Can Do

Call: Call your representatives and demand that they provide $126 million in funding for the ADAP program for the current fiscal year and an additional $244 million in 2011. Phone calls and emails are critical—to find the contact information for your representative, go to www.congress.org and enter your zip code in the upper right corner.

Tell your story: Michael Emanuel Rajner, BSW, an AIDS activist based out of Florida is fielding calls from the media and elected officials about the ongoing ADAP crisis. If you or someone you know is struggling to access HIV medications and wants to share their story, please email Michael merajner@gmail.com or call: 954-288-1999 .

TAG NEW WAYS TO CONTRIBUTE

Supporting TAG is a wise investment in AIDS treatment advocacy. With a small but well-organized and highly respected staff of professionals, every donation to TAG brings us one step closer toward better treatments, a vaccine, and a cure for AIDS. There are several ways you can support TAG today!

Make a tax deductible gift now by credit card using our secure website (www.treatmentactiongroup.org) or by calling Joe McConnell at 212.253.7922 to request a donation envelope.

Celebrate!
Expand your support for TAG by asking your friends and family to make a donation in your honor to celebrate your birthday, anniversary, or the holidays. An acknowledgment will be sent to donors, and you will be informed of gifts made in your honor. Please call Joe McConnell at 212.253.7922 to request that materials be sent to friends and family.

Support TAG's
Research in Action Awards
Each December, TAG's Research in Action Awards event honors some of the most important scientists, artists, celebrities, and activists working for better treatments, a vaccine, and a cure for AIDS. Past honorees and presenters have included New York State Senator Tom Duane, researcher Dr. Trip Gulick, executive director of the Global Fund Michel Kazatchkine, award-winning playwright Terrence McNally, actor David Hyde-Pierce, and stage and screen actress Kathleen Turner, among many other scientists and dedicated AIDS activists. Join us this December!

Does your company have a matching gifts program?
If so, you can double or even triple the donation you make to TAG. If your company offers a matching gifts program, please complete its matching gift form and send it in with your donation to TAG.

Make a gift of stock to TAG
Gifts of stock benefit TAG and the donor. The donor who purchased the stock at a lower price receives the tax deductible benefit of the stock's price on the day it is transferred to TAG.

For more ways to support TAG, please visit our website at www.treatmentactiongroup.org or contact Joe McConnell at 212.253.7922.

TAG BE INVOLVED

About TAG

Treatment Action Group is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS. TAG works to ensure that all people with HIV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end AIDS.

Program areas include antiretroviral treatments, basic science, vaccines, prevention, hepatitis, and tuberculosis.

Join TAG's Board

TAG is always seeking new board members. If you are looking for a great place to invest your time and talents, please call Barbara Hughes, TAG board president, to learn more about board opportunities with TAG.

Call 212.253.7922 or email:
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