

CHOICES

THE NEWSLETTER OF HAWAI'I ISLAND HIV/AIDS FOUNDATION

May-June 2004

Research into microbicides by Gus Cairns

Scientists have started doing proper research on microbicides for anal sex. Microbicides are substances that can be incorporated into lubes or enemas, or used as suppositories, that prevent HIV from getting into the body through the vagina or rectum.

There are numerous candidates being investigated. These range from simple gels that put a physical barrier between HIV and the body to antiviral drugs that neutralize HIV inside rectal membrane cells.

The London Microbicides Conference that took place from March 29 to April 1 devoted its first day to rectal microbicides.

Pamina Gorbach of the University of California, Los Angeles opened by reminding the conference that unprotected anal sex was common in gay men -- with 35-48 percent of U.S. gay men reporting having it in the last year -- but common in heterosexuals too. About a quarter of U.S. women have had anal sex and up to half of women who attend STD clinics. (It was recently even discussed by the girls on "Sex and the City.")

In fact, because there are more heterosexuals than gay men, the number of women practicing anal sex in the U.S. is seven times greater than the number of gay men -- and they are much less likely to use condoms. Women who had anal sex are three to five times more likely than other women to catch HIV.

Sally Blower, also of UCLA, has calculated the likely effect of microbicides. In a high-risk situation like a gay bathhouse, where unprotected sex and HIV transmission is common, even a partially effective microbicide would reduce HIV cases.

She calculated that a microbicide which only stopped 50 percent of HIV transmissions and was only used 50 percent of the time would still reduce the number of new infections by 25 percent.

Alex Carballo-Diéguez of Columbia University in New York said gay men were currently rather skeptical about microbicides and the concept might need to be "sold" to the community. They were used to the 95-98 percent effectiveness of condoms at stopping HIV when used consistently and correctly, and when told that microbicides might not be as effective as condoms, only 25-35 percent of gay men said they'd be interested in using them. Carballo-Diéguez said it should be emphasized that microbicides could be used with condoms as additional protection -- but also as a way of making sex more pleasurable and less risky if condoms were not used. Peter Anton of UCLA outlined the reasons the gut was so good at transmitting HIV. Cells in the wall of the rectum and colon are actually designed to take up foreign particles and transport them to immune cells inside the body to be destroyed, and HIV takes advantage of this. Anal sex almost inevitably causes tiny tears in the rectal lining, too, which HIV can get through. So a rectal microbicide has to have very effective barrier properties but also neutralize HIV inside cells.

CONTENTS

<i>HIHAF</i>	2
<i>Viewpoint</i>	3
<i>Healthy Heart</i>	4
<i>News Items</i>	5
<i>Drug Approval</i>	6
<i>Stories Continued</i>	7
<i>Notices</i>	8

continued on page 7

CHOICES

is a publication of the
Hawaii Island HIV/AIDS Foundation
75-240 Nani-Kailua Dr. Suite 5
Kailua-Kona, HI. 96740
Phone: 331-8177
Fax: 331-0762
E-mail: whaf@whaf.org

P.O. Box 6129
Hilo, HI. 96720
Phone: 981-2428
FAX: 981-2429

Georgie Kennedy/Executive Director

Staff Hilo

Kaiulani Carvalho/Office manager
Lisa Akana, RN/Treatment Advocate
Kate Nawahine/Benefits Specialist
Cindy Medeiros/Shelter coordinator-Medicaid
Lenard Allen/HIV Counseling-Testing
Jeff Seyfried/Prevention Services to PLWH
Cyd Hoffeld/Prevention for women & teens

Staff Kona

Wing Takakuwa/Treatment Advocate
David Braaten/Benefits Specialist
Karen Carder/Prevention & Outreach
Keoni Castillon/Outreach Worker
Gene Smith/Client Services-P4P
Wes Smith/Office Manager
Ginny Cohen/Funds Development
Devin Awong/Youth Coordinator
Geri-Ann Balicki/Administration Assistant

BOARD OF DIRECTORS

Dr. Anne-Marie Muramoto/President
Barbara Zacchini/Secretary
Susanne St. John/Treasurer
Don Sasaki
Philip Hema
Scott Dodd
Dr. James Stanley
Victor Manongdo
Sharon Kensinger
Elwood Kita
Gail Makuakane-Lundin

Editorial Policy

The articles contained in this publication are meant to inform and entertain only. They do not constitute an endorsement. The publication of any name or image does not necessarily imply anything about that persons condition, health or sexual orientation. The opinions expressed are those of individual authors and do not necessarily represent official positions of HIHAF or any other organization mentioned herein.
Contributions of articles and other materials for publication are encouraged and welcomed.

Hawai'i Island HIV/AIDS Foundation

Mission Statement

The Hawaii Island HIV/AIDS Foundation is a non-profit organization dedicated to assisting those affected by HIV/AIDS to maximize their quality of life, and to ending the spread of HIV. We also utilize the lessons learned in the HIV epidemic to care and advocate for others in the fight against related diseases.

Vision

To build a healthier, stronger, and more sustainable community that supports all its members with a focus on HIV issues.

Core Values

Responsiveness: To people with HIV/AIDS and their families and to the prevention education needs of the community.

Accountability: To our consumers, funding sources, and the community at large.

Integrity: To provide services to the entire community in a humane, loving, non-judgmental manner.

Diversity: To embrace the philosophy of "inclusiveness".

Collaboration: To establish and maintain partnerships within the community that maximizes resources and decrease duplication of services.

Leadership: To set the highest standards for responsibility to our mission, vision and values, and be recognized as a positive, inspirational role model in our community.

Advocacy: A collective public voice to speak on behalf of those affected by HIV/AIDS.

*Go confidently in the
direction of your
dreams. Live the life
you have imagined.*

Henry David Thoreau (1817 - 1862)

VIEWPOINT:

New Breath

by Marcelle Mendez

My name is Marcelle. My story is about the breath of life. I want to tell other women who have had multiple challenges in their lives—don't give up on yourself or your family. Learn to forgive, and treasure those moments with each other because they are so precious.

In August of 1997, in a Kona hospital, I almost died of AIDS. I had been sick, losing my hair and body weight since late 1995. I was a single mother with an ADHD teenager, dealing with additional insurmountable stress from extended family members, working an extremely high-stress job that required constant rotating 24-hour shifts, and I was rapidly deteriorating from AIDS. I had a raging fever for seven months and was still working. I had only 35 T-cells, while the average healthy person has approximately 100 T-cells. I didn't tell anyone of my fever, including my family. Nobody asked and nobody noticed. I had to change my life or I was going to die and it was not going to be of AIDS.

By 1996, the 'cocktail' therapy became available which involved several very toxic medications. Like so many other patients, I was taking 30-40 pills a day, fighting, struggling to stay alive, while ironically getting sick from the medication. Some patients died because their bodies were not responding while others couldn't keep up with the strict regimen for the medications to be most effective. By the time I started the meds, it was almost too late.

I had been denying my severely wasting-away body and my hungry soul and it was killing me. It was one of the loneliest times of my life and death was almost an impending relief. It was my son—and only my son—that motivated me to stay alive. In the end, the only thing the dying are concerned about is leaving their loved ones behind in pain and I worried about my son because he had no one. There was nobody who loved, understood, or chose to be as devoted to him as I was. In spite of all my parenting mistakes and controversial decisions, I was the only person qualified who loved him enough to do the job. Because I wanted to give him hope, I reached down deep inside me where only Spirit lives and realized I needed to live for my son. I felt emotionally and spiritually very strong although I was dying. It was if the entire tragedy of my life prepared me for where I decided I wanted to go at this point in my life. The same determination that almost killed me, by giving up on life, was now giving me life.

For women facing adversity:

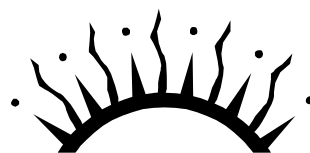
I want women to realize the incredible amount of power they have. They have the choice to control their lives and to have exactly what they want. As a child survivor of sexual molestation, physical abuse and emotional neglect, I had no voice. If you remain silent, you give up your power. Women don't utilize their voice as much or we utilize it in a different way and it doesn't get recognized in society. My challenges have taught me to capture my voice and raise it.

My whole life has been a trauma. HIV/AIDS is just another trauma but being a woman living with it makes it even more challenging because of the isolation. Ironically, the challenge is a gift that empowers me as a woman to choose to come first for the first time in my life. Every woman has so much power in here life. You are worth asking for what you want and getting help and support. You do not have to do it alone. You are a queen. I am a queen. We are queens. HIV/AIDS has given me the opportunity to choose quality of life. I feel I am very much living in the moment. I'm standing on top of the world as I claim my personal power. I don't have power over anybody else but I can choose to create my life as a canvas of truth and health. I want to be a person who evolves. Not in other peoples eyes, only in mine. My life is dedicated to constantly moving forward spiritually.

How I am surviving right now:

With a lot of wisdom, love, compassion, sincerity, and a lot of kick-ass don't f___ with me. I don't have the time. Life is just so precious and it's moving very fast. I don't know if you noticed, but it's moving very fast.

Marcelle Mendez is a self-described "survivor" who lives in Puna and works to inspire other women



Broccoli Attack?

by Tim Gales

When I got pneumonia in '91, I learned I had no T cells. Zero. I expected that would kill me. It never occurred to me that a heart attack might get me first.

But almost ten years later, that's exactly what seemed to be happening. One average winter day, it started to feel like someone was punching me in the shoulder—increasingly hard.

The nurse at LA County's AIDS Clinic asked me if I'd eaten any broccoli. Nope. "What about asparagus or salad?"

Through my misery, I said I thought I was having a heart attack. She told me, "Go home honey, you've got gas," and I obeyed. She was the pro, and besides; Who wants to be having a heart attack? But after another few days of abject agony, I found myself at another hospital being told I'd had one, all *right*—and was still having it.

IS IT THE MEDS?

Both my parents had heart attacks, so there's a family tendency of some kind. And when that punching feeling showed up in my shoulder, I'd been gaining weight, not feeling like going to the gym and ignoring my "lipids" while they went through the roof.

I'd also heard about a possible link between lipids and the particular protease inhibitor (PI) I was on (I'd read a story on the subject in POZ [Heart of the matter, August 1988]). When I discussed it with my HIV doctor, though, he told me it was just talk; The research wasn't in. Not to mention the little matter of this drug having saved my life....

Anyhow, they rushed me into surgery that day, and my cardiologist did some life-saving of his own by inserting stents (wire-mesh inserts) to hold open both my blocked arteries. My heart was immedi-

Having a heart attack taught me to trust my feelings—especially when docs have no easy answers

ately better. And the place in my leg where they'd gone in with the stents healed in two weeks. So I returned to work and went back to the gym.

My cardiologist didn't show any interest at all in the POZ article on Pis I'd brought him, and I complained to my partner, Brian, that his reaction smelled a whiff anti-gay. But I went ahead and changed my meds anyway; my HIV doctor and I decided it seemed like the prudent thing to do.

JUST A HUNCH


It's been three years now, and I feel great. I eat well, go to the gym three to five times a week and concentrate on cardio. I also read my lab results and follow research more closely than I used to. Then again, I still go a lot on feeling.

For instance, I have a hunch my original PI was a factor in my heart troubles, even though I have no proof. When my doctor recently told me about a new combination drug that contained it, I told him I wouldn't be taking it. Ever. He didn't argue.

from POZ, Spring 2004

RAISE YOUR GLASS

THESE DELICIOUS DRINKS CAN ACTUALLY BE GOOD FOR YOUR HEART:

	The Drink	How it works	Daily dose
	Concord Grape juice	New research shows that antioxidants in grape juice may lead to a six-point drop in blood pressure. Drinking the purple stuff can also help slow the process that allows cholesterol to clog your arteries.	12 oz.
	Green or Black Tea	The teas antioxidants appear to reduce the dangerous constriction of blood vessels that occurs after a fatty meal, say researchers from the University of Maryland. Even such slows in blood flow contribute to heart disease.	1 Cup
	Soy Milk	A study from Wake Forrest University in North Carolina revealed that sipping a serving of soy milk that contains 37 mg of isoflavones—plant compounds that keep arteries clear—lowers cholesterol by 8 percent.	1.5 Cups
	Cranberry Juice	The antioxidant power of those little red berries raises your HDL ("good") cholesterol level by 10 percent, translating to a 40 percent decrease in heart-disease risk, according to research from the University of Scranton.	three 8 oz. serv

Early treatment for HIV Act introduced in House
On February 26th, Minority Leader Naancy Pelosi (D-San Francisco) and Congressman James Leach (R-IA) introduced the Early Treatment of HIV Act (ETHA) in the U.S. House of Representatives. Introduced with strong bipartisan congressional support, the bill included 20 Republican and 51 Democratic co-sponsors. If enacted, this legislation would give states the option to provide individuals living with HIV disease—but not sufficiently disabled to have an AIDS diagnosis—health care benefits through Medicaid. States would also receive an enhanced state match rate as an incentive.

Recent studies conducted by Price waterhouse Coopers have found that receiving early treatment for HIV disease significantly delays disease progression, increases life expectancy and is highly cost-effective. Some of the key findings are:

ETHA could reduce the death rate of people living with HIV who are able to access Medicaid by as much as 60%;

The AIDS Foundation expressed tremendous gratitude to Minority Leader Pelosi for demonstrating her sustained national leadership on HIV/AIDS policy and funding concerns by re-introducing ETHA in the 108th Congress. The Foundation urged the federal government to pass ETHA at the earliest opportunity to promote broader guaranteed access to HIV care through the country.

HIV Policy Watch, Feb 2004

Gilead expands patient assistance program

Gilead Sciences on Tuesday announced that it is expanding and simplifying its U.S. patient assistance program, called "Commitment to Access," that provides access for patients who have limited payment options to Gilead medications free of charge. The redesigned program now enables HIV-positive people who meet program criteria to access antiretroviral medications on the same day they visit their physician and receive a prescription. While the patient assistance program has traditionally allowed prescribing physicians to make referrals to the program, it has now been expanded to enable allied health care professionals to serve as patient advocates and also make referrals. In addition to physicians, patients can work with nurses, nurse practitioners, physician assistants, case managers, and social workers to gain access to the pro-

Drugs covered under the program are the HIV nucleotide reverse transcriptase inhibitor Viread, the nucleoside reverse transcriptase inhibitor Emtriva, the AIDS-related cytomegalovirus retinitis treatment Vistide, and the hepatitis B treatment Hepsera. "The redesign of 'Commitment to Access' reflects our dedication to ensuring that people living with HIV have the most rapid access possible to Gilead antiretroviral medications," said John C. Martin, Gilead president and CEO in a press release. "Expedited access to therapy is especially important in the field of HIV, where patients are often not diagnosed until they are quite ill. 'Commitment to Access' helps ensure patients face fewer delays in accessing potentially lifesaving medication."

It's in the news

PACHA calls on White House to back "ABC" HIV prevention model

The Presidential Advisory Council on HIV/AIDS unanimously backed a resolution calling for President Bush to adopt the "ABC--abstinence, be faithful, use condoms" HIV prevention method in the United States, the *Washington Blade* reports. The group, at its March 29-30 meeting in Washington, D.C., supported the HIV prevention model that has been used successfully in Uganda to lower the nation's HIV prevalence rate 66% between 1991 and 2001. The HIV prevention model stresses abstinence for those who are not married, monogamy among those who are married or in committed relationships, and condom use as a fallback option for those in non-monogamous relationships who choose to have sex. The resolution approved by PACHA says Bush and the Department of Health and Human Services should "exercise bold leadership in raising domestic HIV prevention awareness as part of the strategy to reduce new HIV infections...with a long-term goal of no new infections."

PACHA members, urged by group cochair Tom Coburn, a conservative former congressman who opposes homosexuality and has questioned the effectiveness of condoms, also voted to table a resolution calling for Bush to immediately appoint a permanent director of the White House Office of National AIDS Policy, the *Blade* reports. The office has been headed by acting director Carol Thompson since former ONAP director Joseph O'Neill was appointed by Bush to the State Department Office of the Global AIDS Coordinator in August 2003. Coburn, who was the subject of protests by many AIDS advocates when he was appointed PACHA cochair in January 2002, urged that the measure be tabled because he said the White House is actively searching for a new director. The resolution will be considered at PACHA's July meeting.

HOW HIV DRUGS

GET APPROVED

WHY DOES IT TAKE SO LONG TO APPROVE NEW DRUGS? Developing a new drug can take 7 years or more. First, drug companies must find substances that are active against HIV. Most HIV drugs are identified by testing existing drugs for anti-HIV activity (**screening**). A newer method is **rational drug design**. In this process, scientists "build" drug molecules to fight HIV in specific ways. When a promising drug is identified, it goes through **pre-clinical testing**. This involves test-tube and animal studies. These show whether the drug works against HIV and how it works. They also show how it can be manufactured, and make sure it is not too toxic (poisonous). If pre-clinical results are good enough, the drug company files an **Investigational New Drug (IND)** application. Then it starts testing the drug in humans (**clinical trials**). When enough clinical trials are completed, the manufacturer submits an **NDA**, or **New Drug Application**. If the FDA approves the NDA, the drug can be sold to treat specific medical conditions.

WHAT ARE THE "PHASES" OF CLINICAL TRIALS?

There are four phases of human clinical trials. These apply to all drugs, not just drugs for HIV/AIDS. If the results from any phase of testing are not good enough, the company will stop developing the drug.

Phase I trials test the safety of new drugs for humans. These trials record the side effects that occur at different dosages of the drug. Everyone in a Phase I trial receives the new drug, but different participants may get different dosages. The trials usually study less than 100 people, and take less than a year. In Phase I trials, new drugs are given to humans for the first time. People who participate in Phase I trials face the highest risks compared to possible benefits.

Phase II trials can enroll several hundred people and take 1 to 2 years. They study how well the drug works against HIV disease. They also collect more information about side effects. These trials are usually **randomized**. This means that trial participants are divided into two groups that are similar in terms of age, sex, and health. One group receives the study drug. The other group is the reference or **control** group. People in the control group get standard treatment (called "standard of care.") If there is no standard treatment, they may get a dummy medication (called a **placebo**). Trial participants and their doctors usually do not know who is getting the study drug or the placebo. This is called a **blinded** study. Studies are blinded so that the doctors will be totally objective when they evaluate the health of patients in the study.

Phase III trials collect more data on a drug's effectiveness and side effects. These trials can study up to a few thousand people and often last for a year or more. Phase III trials are normally randomized and blinded. Participants might not receive the study drug. With good results in Phase III trials, a manufacturer can apply for FDA approval to sell the new drug.

Phase IV trials are called "post-marketing studies". The regulations for Phase IV trials are not very clear, and they are not conducted very often. Phase IV trials can monitor a new drug's long-term effectiveness and side effects, or how cost-effective it is. They can also compare the new drug to other drugs approved for the same condition.

HOW DO WE KNOW IF A DRUG WORKS?

The FDA used to require trials that measured **clinical endpoints** before approving a new HIV drug. These trials analyze how many people get sicker, develop opportunistic infections, or die. However, these trials take a long time and are very expensive. A faster, cheaper way to test new drugs is by using indirect measures of patient health. These **surrogate markers** are laboratory values such as viral load or T-cell counts. In 1997, the FDA approved the use of surrogate markers for full approval of new HIV drugs.

from page 1

Actual trials of rectal microbicides have gone no farther than animals. One study found that some vaginal microbicides stopped HIV infection of rectal and colonic cells in the test tube. But when the same preparations were tried on mice, nearly all the animals developed some sign of HIV infection, although the microbicides did help lower the number with a detectable viral load.

The most dramatic -- and amusing -- presentation of the day was by Craig Hendrix of Johns Hopkins University in Baltimore, who looked at where semen and microbicides actually went during and after sex.

He paid talented volunteers (delegates speculated he used porn stars) to lube up with microbicides and then simulate sex by vigorous self-administered action with sex toys -- including a simulated ejaculation with artificial sperm. Furthermore, all this was done inside an MRI scan machine.

The results were dramatic: It was found that four hours after sex, both microbicide and sperm had traveled 60 centimeters (two feet) up the colon, nearly to the spleen (on the right-hand side of the body, just under the ribs).

This implies that rectal microbicides might need to be administered as douches or enemas rather than lubes, and also that they need to stay in the gut for some hours after sex.

Microbicides are not expected to come onto the market even for vaginal use until 2010, and the technical challenges in designing one that is safe and effective for anal use means no one is predicting exactly when we'll see one. However, the first serious steps have been taken toward a new HIV prevention technology for gay men -- and researchers are learning a lot more about backdoor action in the process.

from page 6

USING UNAPPROVED DRUGS

There are three legal ways to use drugs that the FDA has not approved to treat your specific health problem:

1. **Expanded Access** is a program where manufacturers provide unapproved drugs to people who cannot take part in a clinical trial and who meet conditions set by the drug manufacturer. The drugs are usually offered at no charge, but your doctor will have to collect information on how you respond to the drug.
2. Drug companies sometimes provide new drugs to people who are very ill and who have no other treatment options. This is called through **Compassionate Use**, also called a "Treatment IND Protocol".
3. Your doctor can write a prescription for any FDA-approved drug, even if you use it for some other medical condition. This is called **off-label use**. There may be no information about how often medications are used off-label, or how well they work.

FOR MORE INFORMATION

The FDA Center for Drug Evaluation and Research has an informative Internet web page: http://www.fda.gov/cder/handbook/dev_rev.htm

The AIDS Clinical Trials Information Service (telephone 1-800-TRIALS-A) provides information on clinical trials in general, and on trials that are currently enrolling participants.

Hawaii AIDS Clinical Trials Unit (737-2751)

Acid Attacks Reported in Kona

Are you cringing before a recent dental estimate? Well, you are not alone. Dental bills continue to skyrocket for the HIV community. One reason may be cottonmouth or dry mouth that we experience when there is not enough saliva to clear the mouth. It results from changed acidity in the mouth and throat that increases the chances for tooth decay and gum disease produced by some bacteria and fungi who like the new environment. Tooth decay can proceed rapidly under these conditions. Symptoms include a sticky, dry feeling in the mouth or throat, cracked lips, a dry tongue or breath that can fell a wild boar.

HIV can cause dry mouth. Add dry mouth as a medication side effect and the tendency to develop dry mouth as we age and it becomes a triple whammy assaulting the health of our gums and teeth. It has been noted that those of us suffering from depression can also experience increased dry mouth.

There are a variety of actions we can take to improve the situation such as not using mouthwash or toothpastes with alcohol or phenol, sugar, sodium lauryl sulphate (a foaming agent that can irritate gum tissue but gives us that comforting feeling that the toothpaste is working!). We can also drink more water and see the dentist to check health status of teeth and gums. Eating carrots and celery can help as they stimulate saliva production. Alcohol, tobacco and caffeine increase the dryness of the mouth.

There are a variety of products available for purchase that claim to combat this condition.

You can check out numerous websites for more information. Just feed "dry mouth" into your search engine. One example is <http://www.agd.org/consumer/topics/drymouth/main.html>.

The Hawai'i Island HIV/AIDS
Foundation offices
will be closed
Monday
May 31
Memorial Day
□
Friday
June 11
King Kamehameha Day

Spring Has Sprung-- So - there must be paper- work!

The good news is that there is not as much Ryan White paperwork this year! Please bring income verification to case managers and sign the current year contract.

Needed are:

Disability: a copy of award letter or bank statement showing deposit in April 2004.

Earned income: a copy of pay stub(s) dated in the month of April 2004.

LTD or disability retirement payments: a copy of award letter or bank statement showing deposit in April 2004.

Please give us a call if you have a question as the Foundation will be unable to assist you with Ryan White funds without the updated income documents and a signed current year contract.

This is also an opportunity to look in the crystal ball to guesstimate what kind of needs you may have this next year and which of those needs may result in access to Ryan White funds.



HIV UPDATE

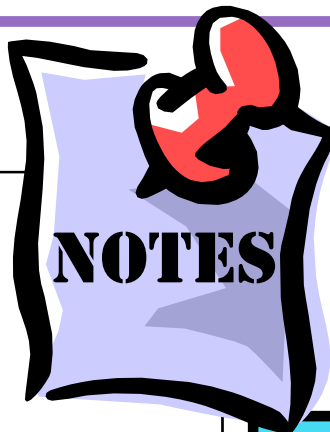
**Tuesday, May 11, 5:30 pm
Kona Board of Realtors office**

**Join us for dinner and a
special speaker, Dr. Michael Harbour.**

Dr. Harbour is an HIV specialist who works in the Positive Care Clinic at Stanford University. He will give us an HIV update focusing on medications; simplifying your medical regime, managing side-effects and new drugs in development.

**RSVP Requested
Call Wing or David 331-8177**

**Dinner and speaker are sponsored by Viread and Emtriva
(Gilead Sciences)**



The Rummage sale was a great success ..Mahalo to all the volunteers and staff who worked so hard.
We cleared over \$1000 to go directly to client services

As always, we have purified water available. Bring your containers to be filled as needed

