POSITIVELY AWARE

THE HIV TREATMENT JOURNAL OF TEST POSITIVE AWARE NETWORK
JANUARY+FEBRUARY 2015

AGING AND HIV

THOUGHTS ON PrEP FROM THE FIRST PERSON CURED OF HIV

ARE YOU AT RISK FOR ANAL CANCER?

LONG-TERM SURVIVORS ARE NOT JUST LIVING LONGER, THEY'RE

KICKING ASS

TEZ ANDERSON AND MATT SHARP
TAKE ON AIDS SURVIVOR SYNDROME

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CORRECTING A CONTRADICTION IN TERMS

Regarding "Can Hepatitis C Be Sexually Transmitted?" in the November+December 2014 issue:

On page 28 the author writes, "We know that HCV is present in blood, but there is no evidence that it is found in semen...." On page 29 the author writes, "Some studies have found HCV in semen, while others have not." The author contradicts himself within two pages. There may be no conclusive or indisputable evidence that HCV is found in semen, but if "some studies have found HCV in semen" then it is false to write that "there is no evidence that [HCV] is found in semen."

On page 30, conspicuously absent from the box "What activities increase the risk of sexually transmitted HCV?" is anal sex without a condom. On page 31 in the box "How to reduce your risk for hepatitis C," point 3 is "wear a condom for anal sex." Clearly, the author indicates in the box on page 31 that he knows that use of a condom during anal sex can reduce risk for sexual transmission of hepatitis C. He should have included in the box on page 30 anal sex without a condom as an activity that increases risk for sexual transmission of hepatitis C.

Additionally, thank you for the photographs and stories included in "A Day with HIV." They are valuable as they ask us to remember the many people affected by this disease and remind us not to focus exclusively on T-cells and antiretrovirals.

—CARL STEIN, MHS, PAC, AAHIVS
PHYSICIAN ASSISTANT
OWEN MEDICAL GROUP
SAN FRANCISCO, CA

Andrew Reynolds responds:

Dear Carl and other readers,

Thank you for the careful reading and feedback on the article "Can Hepatitis C Be Sexually Transmitted?" You are absolutely correct in my contradiction on pages 28 and 29. I should have written that "HCV has been found infrequently in semen and vaginal fluids" or that it is "intermittently found in sexual fluids." I'm honestly not sure how that got past me, so I am grateful for the catch. We will fix this in the online version. As to the box on page 30, my intention was to include activities in conjunction with condomless anal sex that increase a person's risk for sexual transmission of HCV. I will work with the editors at POSITIVELY AWARE to make sure the online version clarifies that to avoid confusion.

—ANDREW REYNOLDS
PROJECT INFORM

SUPPORT

I am so grateful that you have this program to send magazines to positive people who can't afford a subscription. I've been incarcerated for a year and I'm so out of the loop on info, the new treatments and discoveries. Also, the connection with the positive community represented by your magazine was such an inspiration and source of strength and belonging. I miss that so much. Please know that all the hard work that goes into compiling such a class A magazine is not overlooked. May you be blessed.

—CHERYL VITELLO
GATESVILLE, TX

STIGMA

I am currently incarcerated at Collins Correctional Facility in Collins, New York. I want to tell how I was a target of HIV stigma ("Have you ever been the target of HIV stigma or discrimination?" poll, September+October 2014). It started right in my own neighborhood after I disclosed to someone who I thought was a friend. He eventually told some of the other people in the neighborhood, whose cars and homes I would work on, and they started to discriminate. They would no longer shake my hand and wouldn't even allow me in their homes anymore. It angered me because it was clear that my community lacked education on HIV and how it's transmitted or even how it's prevented.

—AUSTIN BELLINGER

LET'S CONNECT.

@POSAWARE

All communications (letters, email, online posts, etc.) are treated as letters to the editor unless otherwise instructed. We reserve the right to edit for length, style, or clarity. Let us if know you prefer we not use your name and city. You can also write: POSITIVELY AWARE, 5050 N. Broadway St., Suite 300, Chicago, IL 60640-3016.

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A model, photographer, or author's HIV status should not be assumed based on their appearance in POSITIVELY AWARE, association with TPAN, or contributions to this journal.

POSITIVELY AWARE
JOURNALISM. INTEGRITY. HOPE.

JEFF BERRY
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@PAeditor
"I love highlighting the efforts of others who are doing groundbreaking work. I feel this issue really accomplishes that."

ENID VÁZQUEZ
ASSOCIATE EDITOR
@enidvazquezpa
"Troubles and concerns are seen as weaknesses, so it's sometimes difficult for survivors to talk about their fears."

RICK GUASCO
CREATIVE DIRECTOR
@rickguasco
"It wasn't until reading this issue's stories about long-term survivors that I realized this is what I've been experiencing myself."

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SINCE 1989. PUBLISHED BY
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SUITE 300
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CHICAGO, IL 60640-3016
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WHO SAID THAT?

QUOTES FROM STORIES APPEARING IN THIS ISSUE

'There are so many lessons to be learned from long-term survivors, and we hope to teach as well as learn.'

MATT SHARP, CO-FOUNDER OF LET'S KICK ASS. **KICKING ASS**, BEGINNING ON PAGE 16

On one hand, it's a definite privilege that we get to worry about aging with HIV, given where we were even 15 years ago. That doesn't allay our simultaneous concerns, however, about the special challenges we'll confront as adults living with HIV enter their 'golden years.'

RICK LOFTUS, MD, IN **AGING GRACIE-FULLY**, BEGINNING ON PAGE 34

Both currently and soon-to-be-available HCV DAAs offer much hope for people living with HIV and HCV. Cure rates look to be very similar to those of mono-infected persons, and the regimens appear to be safe to take with HIV medications and do not impact CD4 counts.

ANDREW REYNOLDS, WRITER AND PROJECT INFORM EDUCATOR. **AASLD CONFERENCE UPDATE**, BEGINNING ON PAGE 46.

'It's something easily transmissible. You don't need to have anal sex to have anal cancer.'

JUSTINE ALMADA, CO-FOUNDER OF THE HPV AND ANAL CANCER FOUNDATION. **ANAL CANCER: ARE YOU AT RISK?**, BEGINNING ON PAGE 20.

'I don't care about what people think about me living with HIV, my life is meaningful, and [just] because of [my] circumstances, you cannot judge me. I can do anything I want to do. I can be anything I want to be, and I'm powerful—and that's what people feel when I speak.'

MARIA DAVIS, HIV ACTIVIST AND SPEAKER. **MARIA DAVIS SPEAKS OUT**, BEGINNING ON PAGE 25.

'There are so many chances when I am vulnerable to HIV. I have to protect myself with those things. PrEP makes me feel like I am in control. It makes me feel empowered.'

BATHABILE, A ZIMBABWEAN SEX WORKER, IN THE **HIVR4P CONFERENCE UPDATE**, BEGINNING ON PAGE 31.

'People wonder, "Why have I tried this hard if my future doesn't look that great?"'

NELSON VERGEL, IN **THE COST OF LONG-TERM SURVIVAL**. BEGINNING ON PAGE 42.

This article will explain why my mindset toward PrEP for sexually active individuals and injection drug users has been transformed dramatically.

TIMOTHY RAY BROWN, KNOWN AS 'THE BERLIN PATIENT.' **THOUGHTS ON PrEP**, BEGINNING ON PAGE 44.

JAN+FEB 2015
VOLUME 27 NUMBER 1

'KICK ASS' PHOTO SHOOT: PHOTOGRAPHER DUANE CRAMER (CENTER) SHOT THE COVER STORY, TAKING TIME FOR A GROUP SELFIE WITH MATT SHARP (LEFT) AND TEZ ANDERSON (RIGHT).

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MY KIND OF LIFE
BY CARLOS A. PEREZ
Dance your ass off.

TELL IT TO ENID
BY ENID VÁZQUEZ
Doctors are long-term survivors who also suffered.

IN THE NOVEMBER+DECEMBER ISSUE, WE ASKED

What do you think are the three biggest issues facing long-term survivors of HIV and AIDS?

We received more responses to this question than to any other poll. The open-ended, multiple-choice nature of our question made compilation of responses difficult. Nevertheless, the usual suspects dominated responses: problems with health care, finance, and social issues (among them stigma, shame, isolation, discrimination, addiction, depression, loneliness, survivor's trauma, and survivor's guilt). Some also mentioned isolation and discrimination specifically from the gay community. Following are a few of the comments from readers.

THIS ISSUE'S QUESTION:

Have you ever had to stop or switch an HIV medication due to side effects?

VOTE AT POSITIVELYAWARE.COM.

The three biggest issues facing long-term survivors of HIV and AIDS? How can anyone figure there are just three issues at the top of a list—it's a very, very long list, to be honest, and no one at this time is doing anything about it besides discussing it. Quality of life, equality, housing, health care, and compassionate outreach. Continuity of care in LGBT-oriented homes. Early aging, isolation... I could go on for days.

Stigma is tops on my list, for it keeps some from seeking care. Lack of funding. Last, but not least, discrimination.

PTSD from watching friends die. The trauma of our own loneliness. Planning for old age after missing many crucial work years to illness.

Poverty; pain (neurological and osteopathic); mental health (depression, anxiety, and survivor guilt).

Aging process. Loss of contact with friends. Lack of adequately trained health care providers.

Internalized stigma from long ago. Survivor syndrome. Fear of living—I thought I was dying for so long, it became a habit.

Few resources and support for female longtime survivors; scarce post-menopause support; poverty.

Emotional and mental health supportive services, especially peer support, to heal from grief and trauma. Prevention of cancer, heart disease, stroke, and diabetes. Financial help after years of illness-related lost employment and education.

1. **The long-term effects of HIV medications.**
2. **Finding and sustaining meaningful long-term relationships.**
3. **Dealing with survivor's guilt—"Why did I live when so many better people died?"**

For someone like me who went on LTD [long-term disability] in the early-mid '90s and having an LTD that only goes to age 65, it is reinventing myself and finding a way to supplement that LTD income once it stops. Having substantial fatigue, my energy is limited and I believe that my mental acuity is somewhat diminished.

Depression and social isolation. Accelerated aging and frailty. Chronic conditions (such as diabetes, cardiovascular disease, and osteoporosis) caused by HIV itself, inflammation, and medication toxicity.

I've been positive for 35 years, and I am dealing with a lot of fatigue, neuropathy, and bowel issues, but my blood work looks fine, so my doctor always thinks that the impact cannot be that much.

Being a survivor of anal cancer and HIV (28 years), I have witnessed the inability or the unwillingness to continue life without a rectum and the absence of anal intercourse. I have seen people just giving in to the outcome of the cancer or disease they have, rather than seek treatment. Quality of life is going to be the main issue with a lot of people.

Health-related issues due to long-term use of ARVs (I've already had both hips replaced at age 52 from Crixivan and have kidney failure from Truvada—what next?).

My three biggest issues have been side effects of the HIV medications causing life-threatening liver and kidney problems, as well as depression related to body-image changes of severe lipodystrophy (and out-of-pocket costs of $14,000 for plastic surgery to slightly mitigate the buffalo hump and turkey-waddle fat deposits), coupled with erectile dysfunction issues and isolation from the gay community at large (all those "D&D-free, UB2" types). HIV hasn't been a walk in the park on a sunny day for me—wish I could report differently.

1. **Mental health, after seeing so many close friends and loved ones die en masse and many of the ones left in depression from survivor's guilt.**
2. **It's very hard to talk about the early days when the "Oh, just take a pill and things will be just fine" mentality is taken by the newly infected.**
3. **A feeling of being alone and forgotten. Some deal with it by doing drugs and drinking too much and other unhealthy activities, to try to block what haunts you when you're left with only your memories.**

A few single answers (some mentioned by several readers): Unresolved lipodystrophy. No work and no disability. Loneliness—a lot of our peers are gone. Pill fatigue. Staying relevant in the fight against HIV. Finding joy and happiness again.

READ ALL THE RESPONSES TO THIS ISSUE'S POLL QUESTION. GO TO POSITIVELYAWARE.COM.

EDITOR'S NOTE
JEFF BERRY

I'M A SURVIVOR

OVER THE LAST 30-plus years I've lost hundreds of friends, acquaintances, and co-workers to HIV and AIDS. In the 25 years since I first tested positive and started treatment, I've developed strange maladies such as thrush, kidney sludge, and shingles. I've been poked, prodded and bled, started and stopped PCP prophylaxis, and made out living wills and medical powers of attorney. I've stood in protest and marched on Washington, walked marathons and participated in a bike ride. I've fallen in love, and broken hearts.

I've probably been on ten different drug regimens during that time, which most likely saved my life but definitely have taken their toll. My viral load is undetectable, and my CD4 T-cells and CD4 percentage are near what a normal, healthy HIV-negative person my age might be expected to have. But as the population of people living with HIV and AIDS ages, we're beginning to understand that there is much more to the story than simply numbers and percentages. Underneath the surface of the syndrome we know as AIDS lies a darker and much more sinister enemy. Those of us who have come through the fight know that enemy intimately, and we have the battle scars to prove it. But we need new tools and weapons to fight it.

I was first diagnosed with post-traumatic stress disorder (PTSD) shortly after I tested positive in 1989 and went into psychotherapy. PTSD, as defined by the Mayo Clinic, is a mental health condition that's triggered by a terrifying event—either experiencing or witnessing it. Not everyone who experiences the event will develop PTSD; they may just have difficulty coping for a while, but eventually they'll adjust and get back to their "normal" life. It's only when symptoms (which can manifest as intrusive memories, avoidance, negative changes in thinking or mood, or changes in emotional reactions) start to cause significant problems in social or work situations and relationships, that it becomes a more serious issue.

While my PTSD was related to childhood sexual abuse, it was triggered by living through a holocaust and ending up testing positive myself. The disorder was no less real to me, however, and I still struggle with the effects to this day.

That's why I was simultaneously elated and deflated when I read some of the many responses to our last poll question (see previous page). We asked individuals what are the three most important issues facing long-term survivors, and I identified with many if not all of them. As I pored through the 10 or so pages of comments, the words loneliness and isolation came up over and over again. I kept thinking to myself, what can we do? How do we reach them and let them know they're not alone?

In this issue of POSITIVELY AWARE you'll meet some of the people who *are* reaching out, and taking matters into their own hands. People like Tez Anderson and Matt Sharp, two amazing individuals who've been through the battle and somehow made it out alive, and who are now using what they've learned to help their fellow warriors, who often feel alone and voiceless. You'll hear from Rick Loftus, HIV activist-turned-physician/researcher, and read about some of the pioneering work he's spearheading in the area of HIV and aging. Activist and author Nelson Vergel talks about the price we're paying for having survived, and the need for special services for AIDS veterans. And long-term survivor and advocate/speaker Maria Davis tells us in an interview how she uses her own story to help others, and to let them know there's hope.

As many people pointed out in response to our poll, our doctors, friends, and family often expect us to just be grateful to be alive. But if being alive means a lifetime of depression, isolation, stigma, survivor's guilt, crippling side effects, and fatigue—just to name a few—it seems reasonable to question if it's worth it.

Just as veterans returning from war may have difficulty re-assimilating, long-term survivors of HIV/AIDS can often feel out of place and useless. We need to be sure that we pay respect to our own soldiers, and let them know we appreciate all that they've been through. We need to set up programs and services designed and tailored specifically to our own unique needs as AIDS veterans. It's time for us to create the structures and support systems that will help our veterans financially, mentally, and physically, well into their golden years. They—we—deserve no less.

It's necessary to hear and share these stories, for they define a generation. We have the opportunity to learn from our past, and to mentor and teach an entirely new generation—while honoring our history, and the fallen.

Take care of yourself, and each other.

Our doctors, friends, and family often expect us to just be grateful to be alive.

FOLLOW JEFF
@PAEDITOR

PHOTO: CHRIS KNIGHT

Briefly

ENID VÁZQUEZ

New version of Stribild

Gilead Sciences filed a New Drug Application with the Food and Drug Administration (FDA) for what amounts to its Stribild single tablet regimen (STR), except that it contains tenofovir alafenamide (TAF) instead of tenofovir DF (TDF). If approved, this would be **the first time that TAF is on the market**. It has been shown to be kinder to the kidneys and bones than TDF, currently on the market under the brand name Viread (also found in Truvada and other HIV medications). The rest of the new medication remains the same: elvitegravir (brand name Vitekta), cobicistat (brand name Tybost), and emtricitabine (brand name Emtriva).

Tests miss some HIV infections

According to a report by I. Chen and colleagues in the December 1, 2014 issue of *JAIDS*, **two men with recently acquired HIV infection came up HIV-negative repeatedly** using both rapid testing and viral load measurements. Reported Abigail Zuger, MD in the *NEJM Journal Watch HIV/AIDS*, "Most new HIV infections are easily diagnosed using the standard algorithms. A few, however, are difficult to pin down, possibly reflecting an early natural viral suppression that may ultimately turn into elite control." The infections were confirmed with a third-generation enzyme immunoassay, a fourth-generation antigen/antibody combination assay, and Western blot testing.

All oral Olysio and Sovaldi

In November, Olysio (simeprevir) and Sovaldi (sofosbuvir) were FDA-approved as an **all-oral, interferon- and ribavirin-free therapy** for the treatment of genotype 1 chronic hepatitis C virus (HCV). Approval was based in part on the results of the COSMOS study, which included people with and without previous HCV treatment, some also given ribavirin (but none had HIV). Recommended treatment is 12 or 24 weeks (the longer duration is for people with cirrhosis). Read more at prn.to/10oHJ3k. For more hepatitis C news see Andrew Reynolds' report from AASLD beginning on page 46.

WHO recommends expanded naloxone access

In November, the World Health Organization issued new guidelines which "aim to reduce the number of opioid-related deaths globally. The guidelines recommend countries expand naloxone access to people likely to witness an overdose in their community, such as friends, family members, partners of people who use drugs, and social workers." WHO noted that such expansion would save 20,000 lives a year in the United States alone. For more, go to who.int/features/2014/naloxone/en/.

HIV therapy lowers risk of stroke

A study from F.C. Chow and colleagues in the November 13, 2014 issue of *AIDS* found that for one San Francisco clinic's HIV patients, undetectable viral load significantly decreased the risk of a stroke. In a review from the *NEJM Journal Watch HIV/AIDS*, Charles B. Hicks, MD commented that, "The mechanism by which ongoing HIV replication increases risk for ischemic stroke is unclear, but persistent **HIV-related inflammation and immune activation likely play a major role**. The strong association of ischemic stroke with hypertension and dyslipidemia in this population reminds us of the importance of aggressively managing these conditions in all HIV-infected patients."

OI guidelines updated

U.S. guidelines for the treatment of HIV opportunistic infections were updated in November. Read "What's New in the Guidelines" at aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/0.

Three drugs better than one to prevent mother-to-child transmission

The National Institutes of Health (NIH) announced that, "For HIV-infected women in good immune health, **taking a three-drug regimen during pregnancy prevents mother-to-child HIV transmission more effectively** than taking one drug during pregnancy, another during labor, and two more after giving birth, an international clinical trial has found." The NIH-sponsored PROMISE (Promoting Maternal-Infant Survival Everywhere) study offers further support for World Health Organization guidelines for preventing mother-to-child transmission, the agency noted. Read more at nih.gov/news/health/nov2014/niaid-17.htm.

Heart disease missed; HAART and aging

See outstanding reports from treatment advocate Theo Smart via TheBodyPro.com, "Cardiovascular Disease Risk Missed in Many HIV-Positive Veterans Despite Better Risk-Assessment Tool" from the 54th ICAAC meeting (bit.ly/11m5jhT) and "Comparing Older and Younger Patients Starting HIV Treatment" (bit.ly/1xzsQsz), looking at a study from Thailand presented at IDWeek 2014. "The number of people living with HIV aged 50 and older is increasing," wrote Smart. "It has been estimated that **by 2015 more than half of the people living with HIV in the U.S. will be over the age of 50**—and their clinical management may be more complicated. In the days before antiretroviral therapy, the progression of HIV disease had been observed to be much more rapid in older patients, and this has remained the case in the era of antiretroviral therapy."

APLA starts new PrEP program

AIDS Project Los Angeles (APLA) announced a new PrEP (pre-exposure prophylaxis) program at the Gleicher/Chen Health Center in Baldwin Hills. According to

PHOTO: CHRIS KNIGHT

an APLA press release, "The Pendleton/Goldman PrEP program [began] serving patients November 17, and will **focus on HIV-negative gay and bisexual men, as well as transgender women**—a population that the Centers for Disease Control and Prevention (CDC) says is statistically at higher risk for HIV. … It educates eligible HIV-negative patients about and offers them access to Truvada—currently the only drug approved for use as PrEP—which is highly effective in preventing sexual transmission of HIV." To make an appointment, call (323) 329-9900, or go to aplahw.org.

Gay dating apps team up with AIDS organizations

"For the first time ever," reported the San Francisco AIDS Foundation (SFAF), "representatives from **seven of the largest gay dating and hook-up websites and apps came together with HIV and STI prevention leaders** from around the country to discuss how to create healthier online communities for gay and bisexual men." Read about the October 2014 meeting in a report at sfaf.org/hiv-info/hot-topics/from-the-experts/hivstd-prevention-online-survey-results.html.

Hep C guidelines updated

The Department of Health and Human Services (DHHS) in November updated the hep C/HIV co-infection section of its HIV treatment guidelines, which now "**emphasizes considerations for use of antiretroviral (ARV) drugs in patients who also receive treatment for HCV infection**. The section includes a new table (Table 12) that provides clinicians with guidance on the concomitant use of HCV drugs and ARV drugs with a focus on potential pharmacokinetic drug interactions." Read the section at aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/26/hiv-hcv.

Chicago man arrested for not disclosing status to sex partner

HIV activists were outraged after a young Chicago man was **arrested at his job for allegedly not disclosing that he had HIV to a sex partner**. The AIDS Foundation of Chicago (AFC) charged mainstream media with driving stigma instead of facts. Read the organization's statement, along with links to other reports, including an *HIV Plus* magazine article detailing potential legal problems with the arrest, at aidschicago.org/inside-story/954-media-driven-stigma-continues-with-new-hiv-criminalization-case.

Illinois to offer PrEP drug assistance program

In December the Illinois Department of Public Health (IDPH) announced that it plans to offer **financial assistance for PrEP** (pre-exposure prophylaxis), beginning in January. Called PrEP4Illinois, this will make it only the second state in the country to have a program like this, the first being Washington state, which rolled out its PrEP Drug Assistance Program in early 2014. IDPH HIV/AIDS Section Chief Mildred Williamson told the *Windy City Times*, "We're incorporating PrEP content into our fundamentals training for organizations that we fund who do HIV testing and counseling. We're also sending a 'dear colleague' letter to medical providers around the state encouraging them to prescribe [Truvada] to high-risk persons they serve." IDPH is also creating a statewide PrEP provider referral list for counselors and their clients.

New HIV documentary points out *It's Not Over*

It's Not Over, a new feature-length documentary from MTV star and award-winning filmmaker Andrew Jenks, was released in October, and will be **distributed globally** by Netflix, SnagFilms, and Pivot TV. Made possible by the MAC AIDS Fund, *It's Not Over* follows the lives of three young people from around the world, including a college girl from the U.S. who was born with HIV. Watch the trailer at itsnotoverfilm.com.

Legal woes unfold for origami condom inventor

The *Washington Free Beacon* reported that, "Origami condom inventor Daniel Resnic will now have to find a third lawyer to take up his case against **accusations that he wasted millions of taxpayer dollars** by using grant money for plastic surgery, lavish vacations, parties at the Playboy Mansion, a Cadillac, and a condo in Provincetown, Massachusetts. The law firm representing Resnic, who received over $2.4 million from the National Institutes of Health (NIH) to develop so-called origami condoms, was granted a motion to be removed as his counsel on Oct. 28 in the Superior Court of Los Angeles." Read the report at freebeacon.com/issues/origami-condom-inventor-dropped-by-second-lawyer/.

SCENE FROM JENKS' *IT'S NOT OVER*.

What is STRIBILD?

STRIBILD is a prescription medicine used to treat HIV-1 in adults who have never taken HIV-1 medicines before. It combines 4 medicines into 1 pill to be taken once a day with food. STRIBILD is a complete single-tablet regimen and should not be used with other HIV-1 medicines.

STRIBILD does not cure HIV-1 infection or AIDS. To control HIV-1 infection and decrease HIV-related illnesses you must keep taking STRIBILD. Ask your healthcare provider if you have questions about how to reduce the risk of passing HIV-1 to others. Always practice safer sex and use condoms to lower the chance of sexual contact with body fluids. Never reuse or share needles or other items that have body fluids on them.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about STRIBILD?

STRIBILD can cause serious side effects:

- **Build-up of an acid in your blood (lactic acidosis),** which is a serious medical emergency. Symptoms of lactic acidosis include feeling very weak or tired, unusual (not normal) muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold especially in your arms and legs, feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.
- **Serious liver problems.** The liver may become large (hepatomegaly) and fatty (steatosis). Symptoms of liver problems include your skin or the white part of your eyes turns yellow (jaundice), dark "tea-colored" urine, light-colored bowel movements (stools), loss of appetite for several days or longer, nausea, and/or stomach pain.
- **You may be more likely to get lactic acidosis or serious liver problems** if you are female, very overweight (obese), or have been taking STRIBILD for a long time. In some cases, these serious conditions have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.
- **Worsening of hepatitis B (HBV) infection.** If you also have HBV and stop taking STRIBILD, your hepatitis may suddenly get worse. Do not stop taking STRIBILD without first talking to your healthcare provider, as they will need to monitor your health. STRIBILD is not approved for the treatment of HBV.

Who should not take STRIBILD?

Do not take STRIBILD if you:

- **Take a medicine that contains:** alfuzosin, dihydroergotamine, ergotamine, methylergonovine, cisapride, lovastatin, simvastatin, pimozide, sildenafil when used for lung problems (Revatio®), triazolam, oral midazolam, rifampin or the herb St. John's wort.
- **For a list of brand names for these medicines,** please see the Brief Summary on the following pages.
- **Take any other medicines to treat HIV-1 infection,** or the medicine adefovir (Hepsera®).

What are the other possible side effects of STRIBILD?

Serious side effects of STRIBILD may also include:

- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do regular blood and urine tests to check your kidneys before and during treatment with STRIBILD. If you develop kidney problems, your healthcare provider may tell you to stop taking STRIBILD.
- **Bone problems,** including bone pain or bones getting soft or thin, which may lead to fractures. Your healthcare provider may do tests to check your bones.
- **Changes in body fat** can happen in people taking HIV-1 medicines.
- **Changes in your immune system.** Your immune system may get stronger and begin to fight infections. Tell your healthcare provider if you have any new symptoms after you start taking STRIBILD.

The most common side effects of STRIBILD include nausea and diarrhea. Tell your healthcare provider if you have any side effects that bother you or don't go away.

What should I tell my healthcare provider before taking STRIBILD?

- **All your health problems.** Be sure to tell your healthcare provider if you have or had any kidney, bone, or liver problems, including hepatitis virus infection.
- **All the medicines you take,** including prescription and nonprescription medicines, vitamins, and herbal supplements. STRIBILD may affect the way other medicines work, and other medicines may affect how STRIBILD works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Do not start any new medicines while taking STRIBILD without first talking with your healthcare provider.
- **If you take hormone-based birth control** (pills, patches, rings, shots, etc).
- **If you take antacids.** Take antacids at least 2 hours before or after you take STRIBILD.
- **If you are pregnant** or plan to become pregnant. It is not known if STRIBILD can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking STRIBILD.
- **If you are breastfeeding** (nursing) or plan to breast-feed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk. Also, some medicines in STRIBILD can pass into breast milk, and it is not known if this can harm the baby.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Brief Summary of full Prescribing Information with **important warnings** on the following pages.

STRIBILD is a prescription medicine used as a complete single-tablet regimen to treat HIV-1 in adults who have never taken HIV-1 medicines before. STRIBILD does not cure HIV-1 or AIDS.

I started my personal revolution

Talk to your healthcare provider about starting treatment.

STRIBILD is a complete HIV-1 treatment in 1 pill, once a day.

Ask if it's right for you.

STRIBILD®

elvitegravir 150mg/ cobicistat 150mg/ emtricitabine 200mg/ tenofovir disoproxil fumarate 300mg tablets

GILEAD

Patient Information

STRIBILD® (STRY-bild)
(elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) tablets

Brief summary of full Prescribing Information. For more information, please see the full Prescribing Information, including Patient Information.

What is STRIBILD?

- **STRIBILD is a prescription medicine used to treat HIV-1 in adults who have never taken HIV-1 medicines before.** STRIBILD is a complete regimen and should not be used with other HIV-1 medicines.
- **STRIBILD does not cure HIV-1 or AIDS.** You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.
- **Ask your healthcare provider about how to prevent passing HIV-1 to others.** Do not share or reuse needles, injection equipment, or personal items that can have blood or body fluids on them. Do not have sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

What is the most important information I should know about STRIBILD?

STRIBILD can cause serious side effects, including:

1. **Build-up of lactic acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take STRIBILD or similar (nucleoside analogs) medicines. Lactic acidosis is a serious medical emergency that can lead to death. Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. **Call your healthcare provider right away if you get any of the following symptoms which could be signs of lactic acidosis:**
   - feel very weak or tired
   - have unusual (not normal) muscle pain
   - have trouble breathing
   - have stomach pain with nausea or vomiting
   - feel cold, especially in your arms and legs
   - feel dizzy or lightheaded
   - have a fast or irregular heartbeat
2. **Severe liver problems.** Severe liver problems can happen in people who take STRIBILD. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Call your healthcare provider right away if you get any of the following symptoms of liver problems:**
   - your skin or the white part of your eyes turns yellow (jaundice)
   - dark "tea-colored" urine
   - light-colored bowel movements (stools)
   - loss of appetite for several days or longer
   - nausea
   - stomach pain

   You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking STRIBILD for a long time.
3. **Worsening of Hepatitis B infection.** If you have hepatitis B virus (HBV) infection and take STRIBILD, your HBV may get worse (flare-up) if you stop taking STRIBILD. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.
   - Do not run out of STRIBILD. Refill your prescription or talk to your healthcare provider before your STRIBILD is all gone
   - Do not stop taking STRIBILD without first talking to your healthcare provider
   - If you stop taking STRIBILD, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking STRIBILD

Who should not take STRIBILD?

Do not take STRIBILD if you also take a medicine that contains:

- adefovir (Hepsera®)
- alfuzosin hydrochloride (Uroxatral®)
- cisapride (Propulsid®, Propulsid Quicksolv®)
- ergot-containing medicines, including: dihydroergotamine mesylate (D.H.E. 45®, Migranal®), ergotamine tartrate (Cafergot®, Migergot®, Ergostat®, Medihaler Ergotamine®, Wigraine®, Wigrettes®), and methylergonovine maleate (Ergotrate®, Methergine®)
- lovastatin (Advicor®, Altoprev®, Mevacor®)
- oral midazolam
- pimozide (Orap®)
- rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- sildenafil (Revatio®), when used for treating lung problems
- simvastatin (Simcor®, Vytorin®, Zocor®)
- triazolam (Halcion®)
- the herb St. John's wort

Do not take STRIBILD if you also take any other HIV-1 medicines, including:

- Other medicines that contain tenofovir (Atripla®, Complera®, Viread®, Truvada®)
- Other medicines that contain emtricitabine, lamivudine, or ritonavir (Atripla®, Combivir®, Complera®, Emtriva®, Epivir® or Epivir-HBV®, Epzicom®, Kaletra®, Norvir®, Trizivir®, Truvada®)

STRIBILD is not for use in people who are less than 18 years old.

What are the possible side effects of STRIBILD?

STRIBILD may cause the following serious side effects:

- **See "What is the most important information I should know about STRIBILD?"**
- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking STRIBILD. Your healthcare provider may tell you to stop taking STRIBILD if you develop new or worse kidney problems.
- **Bone problems** can happen in some people who take STRIBILD. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.
- **Changes in body fat** can happen in people who take HIV-1 medicine. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system** (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

The most common side effects of STRIBILD include:

- Nausea
- Diarrhea

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

- These are not all the possible side effects of STRIBILD. For more information, ask your healthcare provider.
- Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I tell my healthcare provider before taking STRIBILD?

Tell your healthcare provider about all your medical conditions, including:

- If you have or had any kidney, bone, or liver problems, including hepatitis B infection
- If you are pregnant or plan to become pregnant. It is not known if STRIBILD can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking STRIBILD.
  - There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.
- If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you take STRIBILD.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - Two of the medicines in STRIBILD can pass to your baby in your breast milk. It is not known if the other medicines in STRIBILD can pass into your breast milk.
  - Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements:

- STRIBILD may affect the way other medicines work, and other medicines may affect how STRIBILD works.
- Be sure to tell your healthcare provider if you take any of the following medicines:
  - Hormone-based birth control (pills, patches, rings, shots, etc)
  - Antacid medicines that contain aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or after you take STRIBILD
  - Medicines to treat depression, organ transplant rejection, or high blood pressure
  - amiodarone (Cordarone®, Pacerone®)
  - atorvastatin (Lipitor®, Caduet®)
  - bepridil hydrochloride (Vascor®, Bepadin®)
  - bosentan (Tracleer®)
  - buspirone
  - carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®)
  - clarithromycin (Biaxin®, Prevpac®)
  - clonazepam (Klonopin®)
  - clorazepate (Gen-xene®, Tranxene®)
  - colchicine (Colcrys®)
  - medicines that contain dexamethasone
  - diazepam (Valium®)
  - digoxin (Lanoxin®)
  - disopyramide (Norpace®)
  - estazolam
  - ethosuximide (Zarontin®)
  - flecainide (Tambocor®)
  - flurazepam
  - fluticasone (Flovent®, Flonase®, Flovent® Diskus®, Flovent® HFA, Veramyst®)
  - itraconazole (Sporanox®)
  - ketoconazole (Nizoral®)
  - lidocaine (Xylocaine®)
  - mexiletine
  - oxcarbazepine (Trileptal®)
  - perphenazine
  - phenobarbital (Luminal®)
  - phenytoin (Dilantin®, Phenytek®)
  - propafenone (Rythmol®)
  - quinidine (Neudexta®)
  - rifabutin (Mycobutin®)
  - rifapentine (Priftin®)
  - risperidone (Risperdal®, Risperdal Consta®)
  - salmeterol (Serevent®) or salmeterol when taken in combination with fluticasone (Advair Diskus®, Advair HFA®)
  - sildenafil (Viagra®), tadalafil (Cialis®) or vardenafil (Levitra®, Staxyn®), for the treatment of erectile dysfunction (ED). If you get dizzy or faint (low blood pressure), have vision changes or have an erection that last longer than 4 hours, call your healthcare provider or get medical help right away.
  - tadalafil (Adcirca®), for the treatment of pulmonary arterial hypertension
  - telithromycin (Ketek®)
  - thioridazine
  - voriconazole (Vfend®)
  - warfarin (Coumadin®, Jantoven®)
  - zolpidem (Ambien®, Edlular®, Intermezzo®, Zolpimist®)

Know the medicines you take. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. Do not start any new medicines while you are taking STRIBILD without first talking with your healthcare provider.

Keep STRIBILD and all medicines out of reach of children.

This Brief Summary summarizes the most important information about STRIBILD. If you would like more information, talk with your healthcare provider. You can also ask your healthcare provider or pharmacist for information about STRIBILD that is written for health professionals, or call 1-800-445-3235 or go to www.STRIBILD.com.

Issued: October 2013

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KICKING ASS

LONG-TERM SURVIVORS OF HIV/AIDS TAKE CONTROL OF THEIR DESTINY

BY **DAVID DURAN** PHOTOGRAPHY BY **DUANE CRAMER**

In the three decades that our world has been affected by HIV/AIDS, we have seen a rollercoaster of delayed responses, community togetherness, activism, drug advancements, and continued new infections. Thankfully, today's epidemic stands in sharp contrast to the early days of AIDS.

Those who experienced the early years, however, describe it as a battle—a war really—one that claimed too many lives and left a community psychically devastated. For those who managed to make it out alive, especially those who are HIV-positive, life has changed dramatically. What once was a community of support has in some cases left these individuals feeling isolated and disconnected, as priorities in the HIV agenda have shifted. Many of these long-term survivors don't necessarily connect with what's currently happening in the HIV community, and frequently feel abandoned due to their being "healthy" and alive. But what many may not realize is that although these survivors are indeed alive, they aren't necessarily living with perfect mental health. Aside from most long-term survivors, a large percentage of the HIV community has failed to acknowledge that experiencing the traumatic events of the early start of the AIDS epidemic can be devastating, often resulting in serious mental ramifications.

ONE LIFE

After 25 years of living with HIV, Tez Anderson's life had begun to unravel to a point where he contemplated ending it all. "Learning that I was going to live caused more upheavals than learning I was going to die," he said. "I had spent a quarter of a century, over half of my adult life, 'dying,' and I had not planned on living."

Anderson seroconverted in 1983 at the brutal start of the HIV/AIDS epidemic, yet wasn't actually diagnosed until 1986 after moving across the country from Atlanta to San Francisco. A month before his 26th birthday, his doctor told him that he had less than two years to live. During this time period, there weren't treatments like today, and there certainly wasn't a lot of hope for those diagnosed. "I made plans to die," recalled Anderson. "I bought books on death and dying, and even purchased Louise Hay's book on hope, but thought it was the dumbest thing I'd ever seen, and didn't buy into the false version of hope she was selling, so I accepted my fate and made plans to die."

When Anderson hit age 45, he experienced what he describes as a "life crisis"—he wasn't prepared to grow older with this disease that was supposed to take his life many years before. "I found myself terrified that I might grow old with HIV and I had not planned for it," he said. "I'd given up so many hopes and dreams as a young man because I was dying, so I felt bitter and very much duped."

Time passed, and Anderson's depression grew darker and more prolonged. He became detached and withdrawn, and continued to bottle up his feelings as the majority of his support system, including a number of his

TAKING CONTROL: WHEN THEY SAW THAT LONG-TERM SURVIVORS WERE IN NEED OF HELP, TEZ ANDERSON (LEFT) AND MATT SHARP RESPONDED BY FORMING A GROUP.

'WHEN I STARTED TALKING TO FRIENDS AND BEGAN READING REACTIONS TO [SPENCER] COX'S DEATH, I REALIZED I WAS NOT ALONE, AND IT ALL BECAME VERY REAL.'
—TEZ ANDERSON

HIV-positive friends, had died. Although Anderson had managed to overcome the most difficult years of HIV, it wasn't without a struggle. "While I looked fine, I had few T-cells and painful neuropathy, and along the way I had PCP. I lived with 13 T-cells for eight years, I had viral meningitis in 2006, and there were the lesser signs of illness that in my mind signaled impending death—thrush, weight loss, fatigue, etc.," he recalled. Feeling helpless without anyone who could understand what he was going through, Anderson continued to keep his struggles with HIV a secret.

In 2007, Anderson lost his job due to what he described as "mental stress." His friends and co-workers couldn't relate to what he was going through and most wrote him off as just being angry. "I remember being resentful that they thought of themselves as smart people but were clueless about the reality of my life," he said. Anderson was clearly suffering and at one point seemed to be having symptoms of neurocognitive disorders. He once again reached that dark place, and over the next four years became obsessed with killing himself. "I was depressed, anxious, angry, hopeless, and withdrawn, and spent nearly four years in sort of purgatory," said Anderson. "I had alienated most of my remaining long-time friends and 'family of choice' because I had become so ornery and such difficult company."

It wasn't until what seemed to be the lowest point in his life that something sparked while watching a news segment about post-traumatic stress and Iraqi war vets. "They ticked off all my symptoms," said Anderson and proceeded to list them out: "depression, anxiety, anger, loss of future orientation, hopelessness, sleep disturbance, nightmares…and I began to cry."

What Anderson and many others had lived through was a war of sorts—and this revelation is what triggered him to prepare for his next move in life, one that would not only affect him, but help countless others in the process.

SURVIVING A PLAGUE

AIDS activist Spencer Cox died in December 2012, after he stopped taking his medication and is said to have given up. His death shocked treatment advocates. Distraught, they experienced a wake-up call as they hadn't had in years.

Cox wasn't the only long-term survivor giving up. "I lost a lot of my comrades when they turned to drugs and alcohol to try and cope," Anderson recalled.

Wanting to name the thing that was causing long-term survivors to kill themselves, rather than live with the trauma of the loss, grief, and survivor guilt, Anderson and his husband Mark Ruiz came up with AIDS Survivor Syndrome, and freely admits to the awkward acronym. "What we needed was a way to defeat it," he said. "I was slightly obsessing over this idea one morning and thought to myself, 'We need to kick its ass!'"

And in March of 2012, Let's Kick ASS (AIDS Survivor Syndrome) was realized by simply registering the LetsKickASS.org domain online. "When I started talking to friends and began reading reactions to Cox's death, I realized I was not alone, and it all became very real," he recalled.

COMMUNITY SURVIVAL

Anderson was in good company as well. He was meeting with peers from ACT UP Golden Gate, including Matt Sharp, who became the co-founder of Let's Kick ASS (LKA) with him. "We eventually held a first LKA meeting with about 10 people and agreed to hold a town hall meeting to bring together long-term survivors, listen to their needs and concerns, and begin to confront and address the issues," said Sharp. The first planned town hall meeting brought together 250 people. Following is an excerpt from that meeting held September 18, 2013:

The Definition of Brave: "With courage and compassion we survived the darkest days of the plague. Without access to effective treatments, we were forced to rely on each other and ourselves. As individuals and a community, we exhibited strengths we didn't know we had. Now let's all come together again to face the conundrums of midlife and aging to envision our future. As survivors we have valuable lessons to teach our community and the world about living and survival—it's time to embrace our role as elders, teachers, and leaders."

The organization is dedicated to reclaiming lives, ending isolation, and helping long-term survivors envision a future that they once might not have dreamed of. It is raising awareness about the half-million people who came of age during the 1980s and '90s when HIV was considered a death sentence. It's their goal to address the psychosocial, mental, and behavioral determinants of health and illness among long-term survivors everywhere. Their focus is to help heal the trauma of those who survived the AIDS epidemic by bringing people together, building a community, and ultimately making their lives a little better, emulating the same togetherness that brought people together at the height of the epidemic.

LKA is now run by Anderson and Sharp

'WE KNEW WE HAD TOUCHED A NERVE WHEN SO MANY PEOPLE SHOWED UP TO THE INITIAL TOWN HALL MEETING, AND PEOPLE ALL OVER THE COUNTRY STARTED CONTACTING US.'
—MATT SHARP

in a small office in the heart of the Castro neighborhood of San Francisco, one block from where ACT UP Golden Gate once met on a weekly basis. LKA collaborated with the Shanti Project, a 40-year-old peer support organization for those living with HIV or other life-threatening illness, to secure funding for the new organization. Sharp is LKA's only employee, working part-time. Anderson is a volunteer, due to his disability status. In addition to the two co-founders there are other core members who help run the group and organize and plan for the larger town hall meetings. Additional volunteers help with other projects and office duties. LKA does not have a membership process; therefore there are no official members.

Let's Kick ASS is primarily focused on mobilizing the community of long-term survivors, both HIV-positive and HIV-negative, who survived the initial years of the HIV/AIDS epidemic. Coming together to address the many issues of long-term survivors is their top priority.

"Tez and I both experienced and felt many of these issues, but as LKA started mobilizing the community in San Francisco and all over the country, the recognition of these and similar issues has been seen all over," said Sharp. "We knew we had touched a nerve when so many people showed up to the initial town hall meeting, and people all over the country started contacting us once they saw our website and joined our Facebook page."

Together with their team, Anderson and Sharp have accomplished a tremendous amount in a short time. Beyond providing community support and outreach with their gatherings, meditation groups, and outings, in their first year they have held six town hall forums. They also organized the first National HIV/AIDS Long-Term Survivors Awareness Day (June 5, 2014), and a coinciding day-long summit. Additionally, they have helped establish a working group in San Francisco's city council that addresses the needs of aging HIV-positive seniors, and collaborated to create support groups for people age 50 and older in existing nonprofit organizations.

ACROSS THE COUNTRY

"Because of the work we have done over the first year, we have started a movement that has begun to mobilize new chapters in Portland [Oregon] and other cities," said Sharp. "We began to make a place in history; we became part of the HIV/AIDS agenda that had previously been hijacked by the focus on at-risk HIV-negative populations."

Although AIDS survivor syndrome has not yet been officially studied, LKA is working to help change that, especially with regard to the resilience of survivors. "We have ample anecdotal information to let us not delay helping folks restore a sense of meaning and well-being," said Anderson. "People need help now and research is slow…we know it's real as we get letters from people all over the globe, thanking us for validating their experiences." In the meantime, LKA wants to continue to raise awareness of the lives of survivors. "We are a diverse lot—there are a lot of women and transgender survivors—every gender, race, and sexual orientation," Anderson said.

In a short time, Let's Kick ASS has established itself as a much-needed resource and organization for many people living in San Francisco and across the country. "We hope to begin a national network, reaching out to other cities and jurisdictions that hope to begin their own LKA groups," said Sharp. And to help with that goal, they plan on traveling to several cities to help mentor those long-term survivors who are seeking organization. "There are so many lessons to be learned from long-term survivors, and we hope to teach as well as learn," said Sharp.

THE LONG ROAD

Unless you have personally lived and experienced it, it's hard to describe or understand what life was really like before the advancements in HIV treatments emerged. "We were simultaneously patients, caretakers, and warriors when we were young," Anderson said.

He and many other long-term survivors have felt marginalized in the most recent years of the HIV agenda, so many of them living in silence, confusion, depression, and loneliness. What Anderson and Sharp have created together has already changed lives, and will continue to do so as their message of community building and support continues to spread. PA

DAVID DURAN is an LGBT-focused freelance journalist who frequently contributes to such publications as the *Advocate*, *OUT* magazine, *Instinct*, and the *Huffington Post*.

FOR MORE INFORMATION ON LKA, GO TO letskickass.org.

ANAL CANCER: ARE YOU AT

A PAP SMEAR THAT MANY MEN SHOULD GET, TOO

BY ERIN N. MARCUS, MD, MPH, FACP

One recent morning, a group of men and women sat in a clinic reception room, waiting for their Pap smear appointments.

You read that correctly. The Pap smear—a screening test for cervical cancer and longtime fixture of the women's health exam—is now used to detect and prevent cancer of the anus in both men and women. Experts believe that routine Pap testing could play an important role in curbing a doubling of new anal cancer cases that have occurred over the past three decades.

A COMMON VIRUS

While anal Paps are not indicated for most people, there is an increasing consensus that routine screening is important for people at high risk, specifically people whose immune systems are weakened due to HIV infection or medications taken after an organ transplant; men who have sex with men; and women who have cancerous or precancerous abnormalities on their cervical Pap smear.

Yet screening for anal cancer is unavailable in many parts of the U.S., and many people at high risk are unaware it exists.

"The awareness is remarkably low," said Dr. Joel Palefsky, an infectious disease specialist and professor of medicine at the University of California, San Francisco. "Even in San Francisco it's limited, though we have been doing [screening] a long time. The awareness is even lower elsewhere."

Unlike colon and rectal cancer, most anal cancers are caused by a handful of strains of human papilloma virus, or HPV, a common virus (estimated to infect the majority of people in the U.S.) that has hundreds of different subtypes. Cervical cancer is caused by the same HPV strains. Most people clear HPV infections over time. But some are vulnerable to long-term infections that can eventually transform affected cells into invasive cancer.

More than 7,000 new cases of anal cancer are diagnosed in the U.S. each year, and about 1,000 individuals die of the disease annually. Even though a majority of those diagnosed—about two out of three—survive for five years or more, the disease and its treatment can be debilitating. Those who survive may have long-term problems with urination, defecation, and sexual relations. Contributing to the increase in anal cancer are the HIV epidemic and the longer lifespan of people with HIV due to highly active antiretroviral therapy, or HAART; an increase in the number of people with organ transplants may also have contributed.

One study of men with HIV found that anal cancer tended to be diagnosed about 13 years after they were found to be infected with HIV. Among men who have sex with men, anal cancer is now as common as cervical cancer was among women before the Pap smear was developed.

"All you've got to do is see one young guy with anal cancer" to realize the value of screening, said Dr. Elie Schochet, a colorectal surgeon in Fort Lauderdale. "I've had patients come to me with cancer and when I look back through the record, there was an opportunity to take care of this sooner."

WITH OR WITHOUT ANAL SEX

Compared to screening for other cancers, screening for anal cancer is a relatively new phenomenon. Many primary care doctors are unaware of anal cancer screening, and don't routinely ask patients about whether they engage in anal sex, have a history of sexually transmitted infections, or are experiencing anal discomfort. Many doctors don't even feel comfortable performing rectal exams. (Even though a doctor's rectal exam may miss very early disease, some experts believe it is better than nothing in people at risk). Patients may not feel comfortable telling their doctor about their sex practices. Women with a history of cervical Pap smear abnormalities may not realize that they are at risk even if they haven't had anal intercourse, since the virus can spread between the genitals and the anus.

"A huge challenge for us is the stigma that surrounds (anal cancer) and that part of the body," said Justine Almada, who co-founded the HPV and Anal Cancer Foundation with her brother and sister after her mother, who had been treated years earlier for precancerous cervical changes, died of anal cancer at age 53. "It's something easily transmissible. You don't need to have anal sex to have anal cancer."

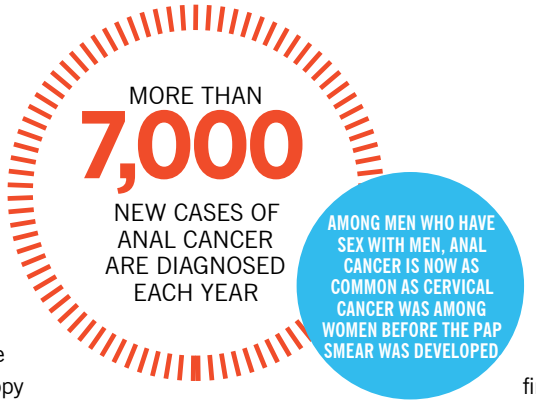
THE RUB

Even if a primary care physician wants to perform an anal Pap on a patient, he or she is placed in a conundrum. If the screening Pap is abnormal, then the next step in the work-up for cancer or pre-cancer is a procedure called a high-resolution anoscopy. But in many parts of the U.S., specialists trained to perform this procedure are scarce or non-existent.

"It's an ethical dilemma for doctors if they diagnose" an abnormality and can't send a patient for anoscopy, said Jeff Taylor, 52, an HIV treatment educator and community member of the National Cancer Institute (NCI)'s AIDS Malignancy Consortium. "There's a lot of frustration because access to [anoscopy] is so sporadic."

Mark Hubbard, who was diagnosed with HIV 27 years ago, learned about anal Pap smears in the late 1990's through his work as a health educator and advocate. He was concerned that he was at increased risk of anal cancer because of his HIV and because he had experienced outbreaks of anal warts, which are caused by different strains of HPV. Until recently, however, he was unable to find anyone in his home state of Tennessee who performed anal cancer screening, and had to travel to Pittsburgh—at a cost of about $500 per trip—to be tested.

RISK?



"A lot of providers were completely clueless and would say crazy things," he said. "Once I decided I really wanted to be screened, I couldn't find anybody."

As with the cervical Pap test, the anal Pap is simple and inexpensive. It involves swabbing the anus with a Dacron swab and then placing the swab in a liquid-filled jar that is the same type used for Pap smear samples. High resolution anoscopy—the next step if an anal Pap is abnormal—isn't complex either, but it requires specialized training for the doctor or nurse. It uses a special microscope that is already widely available in many gynecologists' offices, where it is used for colposcopy, the standard procedure to examine the cervix after an abnormal Pap smear.

THE EXAM

Early last year, I spent a morning watching Dr. J. Michael Berry, a cancer specialist at the University of California, San Francisco, coach a gynecologist and an HIV specialist on how to perform anal Paps and high-resolution anoscopy. The first patient was a middle-aged taxi driver who had recently had a normal colonoscopy. As the patient lay on his side on an exam table, the HIV specialist placed the tip of the scope in his anus and then looked through a connected set of magnifying binoculars, swabbing with an acetic acid-soaked cotton swab and searching for irregular areas. (The rest of us watched on a computer screen that showed what she was viewing.) The affected area turned pale. She took a small sample of the area and then rubbed it with a swab soaked in trichloracetic acid to destroy the abnormal tissue. After 20 minutes, she had finished her examination.

"To be good at this procedure, you have to do it a lot," Berry said. "It's very gentle—most people barely notice."

The patient wondered why the abnormalities hadn't been spotted on his colonoscopy. Berry explained that even though the colonoscope passes through the anus, the purpose of colonoscopy procedures is to examine the large intestine and rectum for cancer. Most colonoscopies don't carefully examine the anus; for them to do so, the colonoscope would have to be turned backward in an unusual position. "Colonoscopy can be misleading," Berry said. "People end up with a false sense of security—they say, 'someone examined my butt and it was fine, so why do you want to look again?'"

CHANGING THE MEDICAL FIELD

Awareness of anal Pap screening has been growing among health workers. Palefsky estimates that he, Berry, and other HPV specialists have trained more than 500 health workers in high-resolution anoscopy. The International Anal Neoplasia Society, the world's first professional group focused on preventing and treating anal cancer, held its inaugural meeting last year. The New York State Department of Health now recommends that HIV-infected men who have sex with men, as well as anyone with a history of anal or genital warts and women with a history of pre-cancerous Pap smear findings, undergo anal Pap testing each year.

"When we first started, it was like, 'I've never seen anal cancer, what kind of nonsense are you talking about?'" Dr. Stephen Goldstone, a New York-based surgeon, said. "But we're developing a critical mass. As the scientific body of evidence has grown, people have started to take notice."

An 8-year, $89 million National Cancer Institute-funded study is now examining whether treating the precancerous anal abnormalities caused by HPV reduces anal cancer in people with HIV. The study plans to enroll more than 5,000 people in 15 sites around the U.S. Scientists hope the study will improve their understanding of the molecular changes that occur as anal cancer develops, help them ascertain whether some biomarkers, or laboratory findings, predict who is at highest risk of developing anal cancer, and find new treatments.

CHANGING THE HIV FIELD

Perhaps most important, the study will provide the "gold standard" clinical trial evidence that the U.S. Preventive Services Task Force and U.S. Centers for Disease Control require in order to decide whether to recommend cancer screening tests. These recommendations significantly sway whether doctors perform the test and influence insurance companies that are considering whether they will pay for the test (at present, many companies will pay for treatment of an anal abnormality but not for screening to look for that abnormality). While it may seem intuitive that early treatment of precancerous anal lesions reduces a person's likelihood of developing cancer, proof is needed that the benefits of such therapy outweigh the harms, when performed on a massive scale.

The need for such a large study is frustrating for some advocates, who point out that the cervical Pap smear, which has been credited with saving millions of women's lives, was introduced into routine practice without such rigorous, population-based evidence. But Hubbard said he hopes the study's findings will lead to the widespread use of guideline-based, standardized treatments.

"Cervical dysplasia was treated for years without that evidence," he said, but added, "people tend to overtreat when they don't know what they're doing. There are a lot of horror stories in the community about bad treatment. This is a really important study." PA

ERIN N. MARCUS, MD, MPH, FACP, is a general internist at the University of Miami Miller School of Medicine and writes about public health. The reporting of this article was supported by a grant from the Ford Foundation.


ISENTRESS®
raltegravir film-coated tablets 400 mg
Hey Date Night! I love spending time with you.
I was ready to learn more about my HIV treatment options. So I spoke to my healthcare professional and we chose ISENTRESS as part of my HIV regimen. He told me it could fight my HIV and may fit my needs and lifestyle.
I can't wait to see you next time.
HIV Positive Model

In a clinical study lasting more than 4 years (240 weeks), patients being treated with HIV medication for the first time demonstrated that ISENTRESS® (raltegravir) plus *Truvada*®:

- May reduce viral load to undetectable (less than 50 copies/mL)
- May significantly increase CD4 cell counts
- ISENTRESS may not have these effects on all patients
- Patients had a low rate of these moderate-to-severe common side effects (that interfered with or kept patients from performing daily activities): trouble sleeping (4%), headache (4%), nausea (3%), dizziness (2%), and tiredness (2%).

INDICATION

ISENTRESS is a prescription HIV-1 medicine used with other antiretroviral medicines to treat human immunodeficiency virus (HIV-1) infection in people 4 weeks of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if ISENTRESS is safe and effective in babies under 4 weeks of age.

The use of other medicines active against HIV-1 in combination with ISENTRESS may increase your ability to fight HIV.

ISENTRESS does not cure HIV-1 infection or AIDS.

You must stay on continuous HIV therapy to control HIV-1 infection and decrease HIV-related illnesses.

IMPORTANT RISK INFORMATION

- Some people who take ISENTRESS develop serious skin reactions and allergic reactions that can be severe, and may be life-threatening or lead to death. If you develop a rash with any of the following symptoms, stop using ISENTRESS and call your doctor right away: fever, generally ill feeling, extreme tiredness, muscle or joint aches, blisters or sores in mouth, blisters or peeling of skin, redness or swelling of the eyes, swelling of the mouth or face, problems breathing.
- Sometimes allergic reactions can affect body organs, such as your liver. Call your doctor right away if you have any of the following signs or symptoms of liver problems: yellowing of your skin or whites of your eyes, dark or tea-colored urine, pale-colored stools (bowel movements), nausea or vomiting, loss of appetite, pain, aching or tenderness on the right side of your stomach area.
- Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having new symptoms after starting your HIV-1 medicine.
- People taking ISENTRESS may still develop infections or other conditions associated with HIV infections.
- The most common side effects of ISENTRESS include: trouble sleeping, headache, dizziness, nausea, and tiredness. Less common side effects include: depression, hepatitis, genital herpes, herpes zoster including shingles, kidney failure, kidney stones, indigestion or stomach area pain, vomiting, suicidal thoughts and actions, and weakness.
- Tell your doctor before you take ISENTRESS if you have a history of a muscle disorder called rhabdomyolysis or myopathy or increased levels of creatine kinase in your blood.
- ISENTRESS Chewable Tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with phenylketonuria.
- Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking ISENTRESS. This may be signs of a rare serious muscle problem that can lead to kidney problems.
- These are not all the possible side effects of ISENTRESS. For more information, ask your doctor or pharmacists. Tell your doctor if you have any side effect that bothers you or that does not go away.
- Tell your doctor about all your medical conditions, including if you have any allergies, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. ISENTRESS is not recommended for use during pregnancy. Women with HIV should not breastfeed because their babies could be infected with HIV through their breast milk.
- Tell your doctor about all the medicines you take, including: prescription medicines like rifampin (a medicine commonly used to treat tuberculosis), over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take any of these medicines: rifampin (Rifadin, Rifamate, Rifater, Rimactane), an antacid medicine that contains aluminum or magnesium, a cholesterol lowering medicine (statin), a medicine that contains fenofibrate (Antara, Lipofen, Tricor, Trilipix), gemfibrozil (Lopid), a medicine that contains zidovudine (Combivir, Retrovir, Trizivir).

  You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call FDA at 1-800-FDA-1088.

Please read the Patient Information on the adjacent page for more detailed information.

Need help paying for ISENTRESS? Call 1-866-350-9232

Talk to your healthcare professional about ISENTRESS and visit isentress.com.

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MERCK

Patient Information
ISENTRESS® (eye sen tris) (raltegravir) film-coated tablets

ISENTRESS raltegravir film-coated tablets 400 mg

Read this Patient Information before you start taking ISENTRESS and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is ISENTRESS?
ISENTRESS is a prescription HIV medicine used with other antiretroviral medicines to treat Human Immunodeficiency Virus (HIV-1) infection in people 4 weeks of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if ISENTRESS is safe and effective in babies under 4 weeks of age.

When used with other HIV medicines to treat HIV-1 infection, ISENTRESS may help:
- reduce the amount of HIV in your blood. This is called " viral load".
- increase the number of white blood cells called CD4+ (T) cells in your blood, which help fight off other infections.
- reduce the amount of HIV-1 and increase the CD4+ (T) cells in your blood, which may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

ISENTRESS does not cure HIV-1 infection or AIDS.

You must stay on continuous HIV therapy to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:
- Do not share needles or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

What should I tell my doctor before taking ISENTRESS?
Before taking ISENTRESS, tell your doctor if you:
- have liver problems
- have a history of a muscle disorder called rhabdomyolysis or myopathy
- have increased levels of creatine kinase in your blood
- have phenylketonuria (PKU). ISENTRESS chewable tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ISENTRESS can harm your unborn baby.
  Pregnancy Registry: There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take ISENTRESS.**
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - It is not known if ISENTRESS passes into your breast milk.
  - Talk with your doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take, including: prescription and over-the-counter medicines, vitamins, and herbal supplements. ISENTRESS and certain other medicines may affect each other causing serious side effects. ISENTRESS may affect the way other medicines work and other medicines may affect how ISENTRESS works.

Especially tell your doctor if you take any of these medicines:
- rifampin (Rifadin, Rifamate, Rifater, Rimactane)
- an antacid medicine that contains aluminum or magnesium
- a cholesterol lowering medicine (statin)
- a medicine that contains fenofibrate (Antara, Lipofen, Tricor, Trilipix)
- gemfibrozil (Lopid)
- a medicine that contains zidovudine (Combivir, Retrovir, Trizivir)

Ask your doctor or pharmacist if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine. Do not start any new medicines while you are taking ISENTRESS without first talking with your doctor.

How should I take ISENTRESS?
- Take ISENTRESS exactly as prescribed by your doctor.
- **Do not** change your dose of ISENTRESS or stop your treatment without talking with your doctor first.
- Stay under the care of your doctor while taking ISENTRESS.
- ISENTRESS film-coated tablets must be swallowed whole.
- ISENTRESS chewable tablets may be chewed or swallowed whole.
- ISENTRESS for oral suspension should be given to your child within 30 minutes of mixing. **See the detailed Instructions for Use that comes with ISENTRESS for oral suspension**, for information about the correct way to mix and give a dose of ISENTRESS for oral suspension. If you have questions about how to mix or give ISENTRESS for oral suspension, talk to your doctor or pharmacist.
- **Do not switch between the film-coated tablet, the chewable tablet, or the oral suspension without talking with your doctor first.**
- **Do not** run out of ISENTRESS. Get a refill of your ISENTRESS from your doctor or pharmacy before you run out.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not double your next dose or take more ISENTRESS than prescribed.
- If you take too much ISENTRESS, call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of ISENTRESS?

ISENTRESS can cause serious side effects including:
- **Serious skin reactions and allergic reactions.** Some people who take ISENTRESS develop serious skin reactions and allergic reactions that can be severe, and may be life-threatening or lead to death. If you develop a rash with any of the following symptoms, stop using ISENTRESS and contact your doctor right away:
  - fever
  - generally ill feeling
  - extreme tiredness
  - muscle or joint aches
  - blisters or sores in mouth
  - blisters or peeling of the skin
  - redness or swelling of the eyes
  - swelling of the mouth or face
  - problems breathing

  Sometimes allergic reactions can affect body organs, such as your liver. Call your doctor right away if you have any of the following signs or symptoms of liver problems:
  - yellowing of the skin or whites of your eyes
  - dark or tea colored urine
  - pale colored stools (bowel movements)
  - nausea or vomiting
  - loss of appetite
  - pain, aching, or tenderness on the right side of your stomach area
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having new symptoms after starting your HIV-1 medicine.

The most common side effects of ISENTRESS include:
- trouble sleeping
- headache
- dizziness
- nausea
- tiredness

Less common side effects include:
- depression
- hepatitis
- genital herpes
- herpes zoster including shingles
- kidney failure
- kidney stones
- indigestion or stomach area pain
- vomiting
- suicidal thoughts and actions
- weakness

Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking ISENTRESS. These may be signs of a rare serious muscle problem that can lead to kidney problems.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ISENTRESS. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ISENTRESS?

Film-Coated Tablets:
- Store ISENTRESS Film-Coated Tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ISENTRESS and all medicines out of the reach of children.

General information about ISENTRESS

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use ISENTRESS for a condition for which it was not prescribed. Do not give ISENTRESS to other people, even if they have the same symptoms you have. It may harm them.

You can ask your doctor or pharmacist for information about ISENTRESS that is written for health professionals.

For more information go to www.ISENTRESS.com or call 1-800-622-4477.

What are the ingredients in ISENTRESS?

ISENTRESS film-coated tablets:

Active ingredient: raltegravir
Inactive ingredients: calcium phosphate dibasic anhydrous, hypromellose 2208, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer 407 (contains 0.01% butylated hydroxytoluene as antioxidant), sodium stearyl fumarate.
The film coating contains: black iron oxide, polyethylene glycol 3350, polyvinyl alcohol, red iron oxide, talc and titanium dioxide.

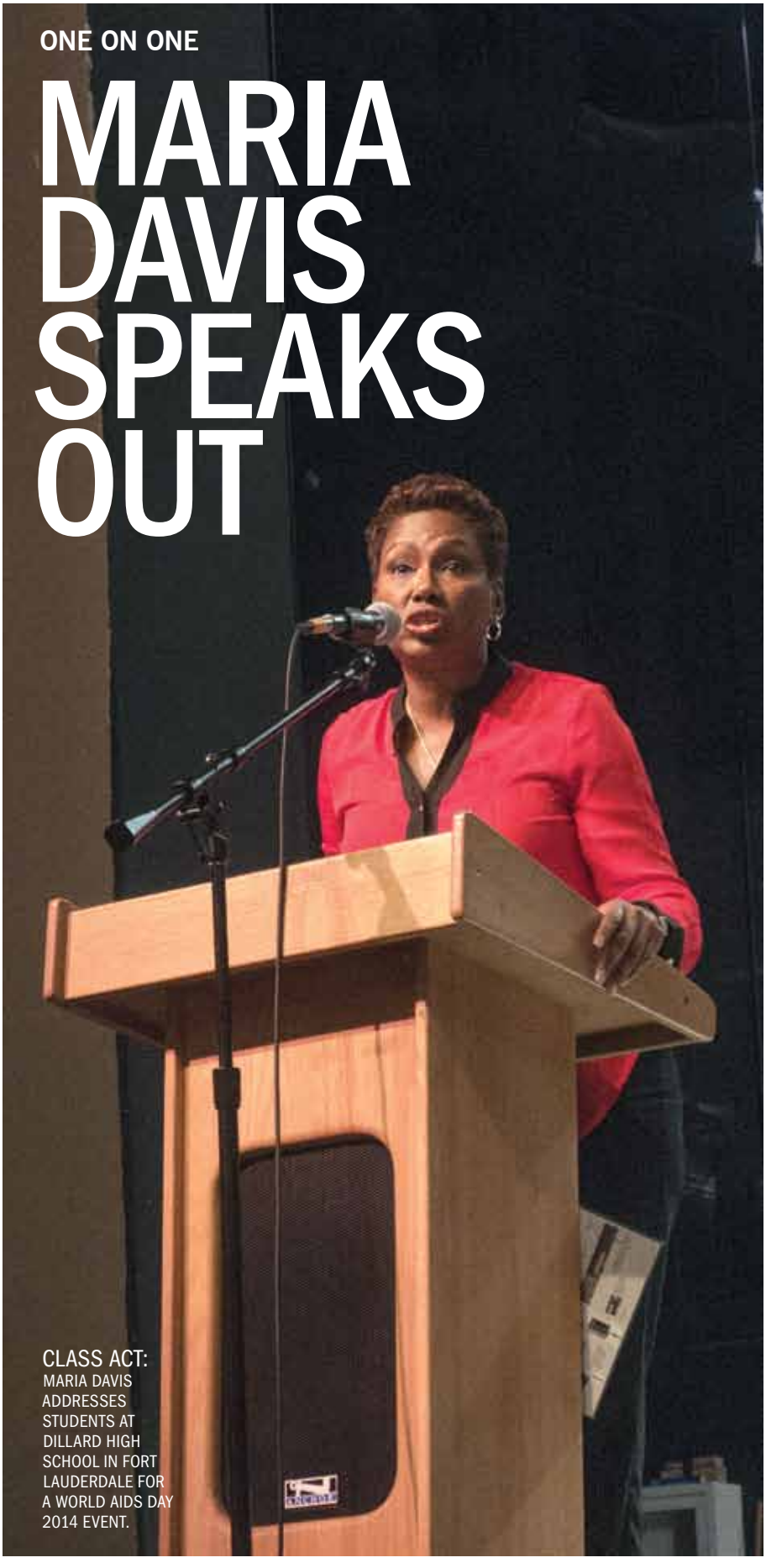
This Patient Information has been approved by the U.S. Food and Drug Administration.

Distributed by:

Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc**.
Whitehouse Station, NJ 08889, USA

Revised December 2013
USPPI-MK0518-MF-1312R025

MARIA DAVIS SPEAKS OUT



CLASS ACT: MARIA DAVIS ADDRESSES STUDENTS AT DILLARD HIGH SCHOOL IN FORT LAUDERDALE FOR A WORLD AIDS DAY 2014 EVENT.

A LONG-TERM SURVIVOR AND ACTIVIST OPENS UP ABOUT LIFE, LOVE, AND HIV—AND WHY WE NEED TO KEEP THE CONVERSATION GOING

INTERVIEW BY **JEFF BERRY**
PHOTOGRAPHY BY **DUANE CRAMER**

At the U.S. Conference on AIDS in October, Maria Davis spoke candidly about her experiences with HIV/AIDS to an audience of her peers. Many were hearing her speak for the first time, but Davis has been speaking out about HIV for years. POSITIVELY AWARE *caught up with her recently to talk about the work she's been doing, and why she is so passionate about helping others navigate their own journey.*

JEFF BERRY: When you first walked out on stage at the U.S. Conference on AIDS in San Diego, it was very emotional, not only for you but for many in the audience. Can you tell us what you were thinking in that moment, and why that experience was so emotional for you?

MARIA DAVIS: I was just thinking about my life and when I was first diagnosed, not thinking I would be living all that I've lived. Being in front of people that believed in the same thing I believe in … they're there because they care. In the beginning when I first got diagnosed I was afraid to tell anybody and I didn't think anybody cared. So just to be in front of so many people and the love that I received from the room—I *felt* it. It was so strong.

Backing up a little bit—can you tell us a little about yourself for people who may not know you?

Well, I'm now what they call a promoter [laughs]. I started out modeling, which led me into being a promoter because I love music. My family, my mother, always had music in the home. I grew up on music, thinking I was an artist, every day singing, microphone in my hand, trying to do

We've all been traumatized in our lives, and how does that trauma affect our

Michael Jackson steps. So I always loved music and I loved to talk and meet people. So being a promoter was so perfect for me. And then meeting so many industry people, [such as] Puffy, and being in the offices of powerful people, sometimes seeing the artist's information not being handled properly, caused me to be a promoter and say, "You know what? I have influential friends in the business. I can get them to my club and I can get some of these unsigned artists to come in and showcase their music in front of them." That went into teaching artists about publishing and always having to be onstage, in front of the stage, but most important, about speaking up. Reading those little fine lines in contracts, and that went into also getting signed artists to be on my show—I had people from Jay Z to 50 Cent. A good friend of mine was at a club called Sweetwater and she kept begging me, "Maria, Maria … you need to do your own show," and I said, "Ohhh … okay, okay." I kept putting it off and then one day I just decided to do it, and that started in March 1994. I'll never forget it.

[With] the success of Mad Wednesdays and [having] three children while being a model, I just decided if anything happens to me, I want them to be taken care of, so I decided to apply for a life insurance policy—and it was a very large life insurance policy. There was a requirement that you take an HIV test. Of course, I took the test in 1995 with no problem. I had heard about HIV, but it was all about AIDS at that time, and there wasn't much information. *I didn't think that I was a person who was at risk.* I don't have HIV. I don't have AIDS. So I took the test and days later it came back in the mail saying, "Dear Miss Davis, We're sorry to inform you … first, we reject you. We can't offer you a policy. We also want to let you know you tested positive for HIV antibodies. Please seek help. Here's a …" I think it was an 800 number. But I was so shocked and surprised. Standing in the post office by myself, nobody to talk to around me. What am I going to do with this? How am I going to tell my children? What am I going to do? And so I sat on that letter for a while. I was in a relationship with someone and I had to tell them that they had to be tested. And the *crazy* part about it was that because we didn't have any information, we both went to the health department. We got tested and they said, "Which one of you wants to come in and get your results first?" He went in and came out—"Ahhh! I'm negative!" I was like, "Yes! That was a lie! I'm *not* HIV-positive. I *don't* have HIV." When I went in the office the woman said, "Miss Davis, we're sorry to tell you that you are HIV-positive." My whole … I can't even … I mean, my heart dropped to the floor. That was crazy, because that was one of my first lessons—that you can be in a relationship with someone and you could be positive, or they could be positive and you could be negative, and that was very confusing to me.

So fast forwarding, [I didn't get] into care immediately. A concerned friend told me about an organization called Friends in Deed, and I started going to their groups for people who were HIV-positive and living with AIDS. I kept going to the group and going to the group and you know, not connecting, because I was trying to figure out why I had this. They felt because I wasn't responding, just sitting there, that I needed to be in crisis counseling, because they knew that I wasn't taking any medication and I was losing a lot of weight.

I remember Scott was the gentleman I came to see, and he looked at me and said, "I'm going to talk to you just like you were my sister." He said, "If you don't find a doctor, if you don't get into care, and start on treatment, you're not going to be here to see your children." I had never thought about that. Wow. See my children? I'm not going to see my children? That day I promised myself that I would find a doctor and they helped me find one. I was scared. I didn't know what I was going to ask the doctor when I got into the office. That's why Merck's *IDesign* campaign is so perfect, and I love working with it. Because I remember how I felt walking into that doctor's office for the first time, not knowing what questions to ask, not knowing *anything*. The campaign has a desktop and mobile app, a medication checklist, and conversation worksheets that you can download and take into the doctor's office with you. You don't have to be afraid. The doctors can download it. The social workers can encourage their clients to do it. I think it's just such an important piece for people who are living with HIV to empower them to have open, honest, and meaningful conversations with

their doctor about how they're doing and feeling on their treatment plan, and if their treatment is individualized for them. What are you going through?

I'm aging right now. I'm over 50. I feel good. But menopause is one of the first things on my mind, and how is that going to affect my treatment? I have to talk to my doctor about that. All of the things, the concerns, that come with aging, are so important to talk to your doctor about. I'm a woman, and I have unique needs that are different than a man's needs. Some women

decision-making?

become pregnant, and maybe need to be on a different treatment plan. It's important for African American women, who are disproportionately impacted by HIV. So that's my reason for being part of *IDesign*, but not my only reason. I *want* to talk to people living with HIV. You mean something. Your life is worthy, so take care of yourself. Make sure that your unique needs reflect your treatment and talk to your doctor, *and don't be afraid*.

Your story is very inspiring and strikes a chord with so many people, especially women who are living with HIV. Why do you think others can so readily relate to your story?

Because I'm honest, I'm truthful, and I don't hold back. I'm not afraid and I don't care about stigma. I don't care about what people think about me living with HIV—my life is meaningful, and [just] because of [my] circumstances, you cannot judge me. I can do anything I want to do. I can be anything I want to be, and I'm powerful—and that's what people feel when I speak.

That's a great message. You could have remained silent about your status, but you chose not to. What prompted that decision?

[Chuckles.] It was so funny. One day I was in a hospital and I don't know why … I was watching television this particular day and they had something on about HIV. I don't recall what it was and I thought to myself, "They need to hear my story. They need to hear from someone who's HIV-positive." There weren't a lot of people talking about having HIV except for Magic Johnson. Very few. I didn't know any women. Magic Johnson was the only man that I knew. I felt it was important for me to tell my story to help other people that were living with HIV, especially women. You don't have to be afraid. Your circumstances do not determine your destination in life. So I felt that if I lift my voice, if I spoke up, that that would encourage other people to speak up. There would be a domino effect.

I do a lot of work in my community—I live in Harlem. When I first joined First Corinthian Baptist Church in Harlem, there might have been 600 members and I remember going up to my pastor, Michael A. Walrond, Jr., and saying, "Listen, y'all have an HIV ministry here? We ought to do something about that. What you doing in church about HIV?" [Laughs.] And he was like, "No, what y'all doing about HIV?" So he let me do whatever I wanted to do. I brought in my doctor at the time, Dr. Theresa Mack. We brought in programs and talked about prevention, and testing. After that, people would come in and say, "I'm HIV-positive [whispering]. What can I do to help? I don't want anyone to know." So we had to meet people where they were. We didn't force people to share their story about being HIV-positive.

You've talked very publicly and candidly in the past about the conversations that we need to have with today's youth. How does that work out when, for example, you're working with a religious or faith-based organization—are they receptive? It sounds like they are, but have there been any instances where that's been a challenge for you?

Uh-huh. Because sexuality is a hard conversation. People don't want to let people know what they do behind closed doors. My

MARIA DAVIS (FAR LEFT) AND PHOTOGRAPHER DUANE CRAMER (THIRD FROM RIGHT) WITH DILLARD HIGH SCHOOL STUDENTS FOLLOWING THEIR WORLD AIDS DAY PROGRAM.

point is, I'm not here to judge you. I'm here to try to help you make better choices that don't hurt your future. HIV is a preventable disease. You have to protect yourself—but first of all, more importantly, to love yourself enough to *want* to protect yourself. There are so many other things in our community that cause people to make choices that might not be positive. So, I try to get people to talk about that, because we might need help in different areas. There are a lot of different issues in our community, especially in the African American community. One of the biggest issue is mental health. We've all been traumatized in our lives, and how does that trauma affect our decision-making? That's very important. Being diagnosed in 1995—that was trauma to me. So what kind of help did I need to get to make sure I was back on the right track? That doesn't affect my choices? Being afraid doesn't mean that I have to bow down to what somebody asks me to do. So how I felt is what I talk to my young people about. You don't have to be afraid to speak up. Let someone know that you need help. This way, they feel comfortable, and let somebody know, "You know what? You want to have sex with me without a condom. That's a no-no. I love me. I wanna live. I'm not gonna let you use me. I'm not gonna let you use my body. I don't have to use sex to pay my rent and my bills and to eat. There's help for me."

It's so important for us to share this information and to just love each other. That's the most important thing to me, that we show each other love and compassion. We don't judge people, whatever their circumstance may be. Everybody is a human being and they deserve the right to live.

What is the most important message that you would like other women to know or to hear?

That love is very important, and that we treat each other with love, and we're careful about what we say and how we say it to people. If your words are negative, think about it before they come out of your mouth. Support people who are living with HIV, and support people who are living with AIDS.

Can you describe the work that you're doing now, such as with the Positive Women's Network-USA?

Positive Women's Network is doing the same work that I'm doing, in different parts of the country. Their mission is to empower women who are living with HIV to be leaders in our community, and I'm a leader in my community, and they're just doing great work.

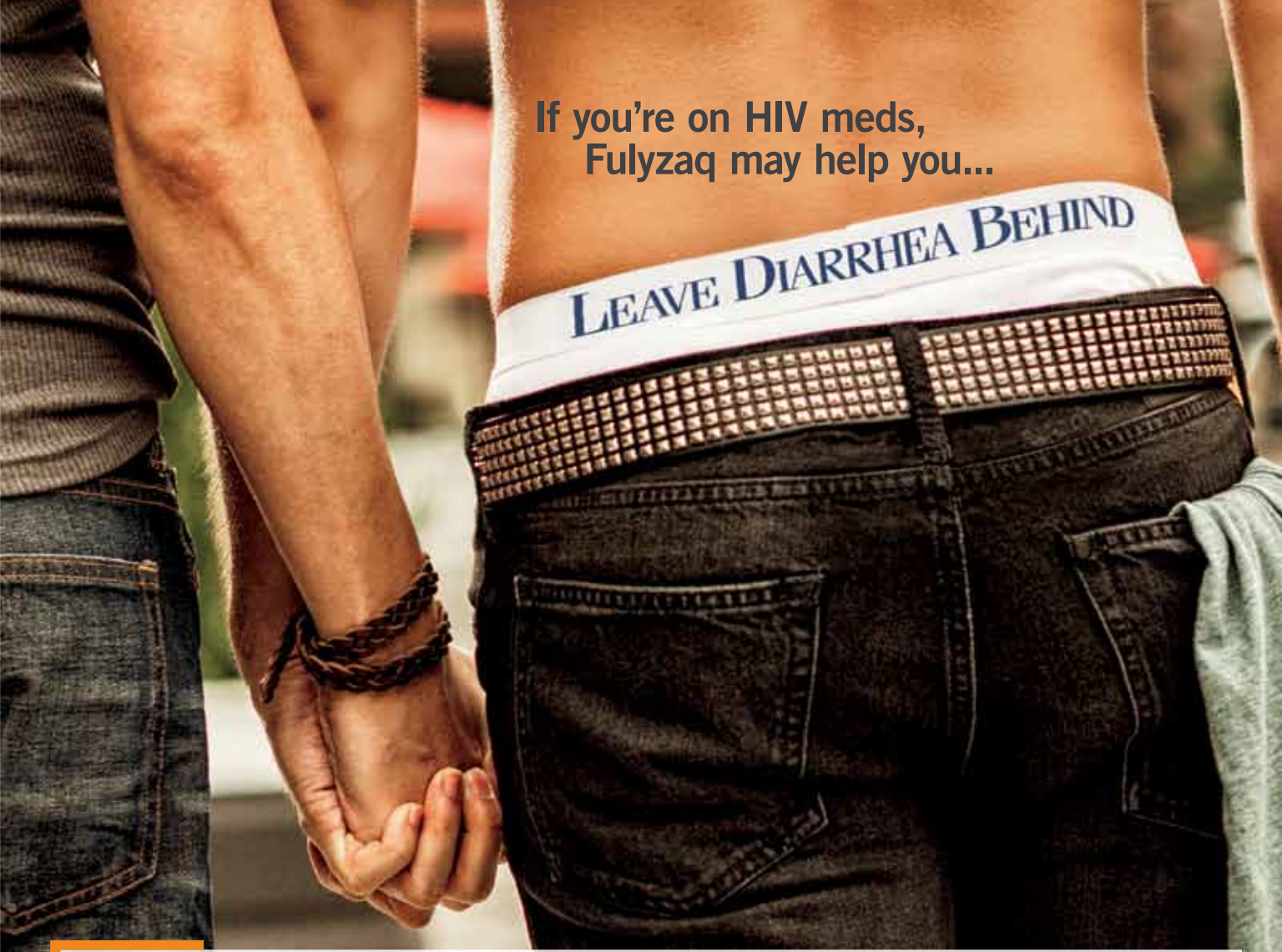
World AIDS Day is coming up and that's so important. Other than my birthday, that's one of my biggest days of the year that I really love. To honor my friends who are no longer here, and to honor those living with HIV and AIDS who are still here, and to empower our community—and to keep HIV in our conversations. I think people are talking less and less about HIV. They say now that it's just a chronic illness, but it's not. There's a stigma. The stigma is still there.

Good point.

People are still in hiding. I still get people telling me every day, "[Whispers] I'm HIV-positive. I'm still not ready to talk about it." We shouldn't even have that anymore. People shouldn't be afraid to talk about their status.

Knowledge is power, and knowledge is life—and that's so important. Love is life. So let's get knowledge, let's love, and let's *live*. PA

PHOTO COURTESY OF DUANE CRAMER



Is diarrhea holding you back? If you are on HIV medications, Fulyzaq is a plant-based, FDA-approved prescription medication that may help manage your diarrhea.

Fulyzaq may help manage your diarrhea over time by making your bowel movements less frequent and loose. Fulyzaq works by normalizing the flow of water in your gut. Fulyzaq did not interfere with commonly used HIV medications, and did not affect CD4 count or viral load in a 4-week study.

It's time to stop dealing with diarrhea and 'Start the Conversation' about Fulyzaq today.

Indication
FULYZAQ® (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.

Important Safety Information about FULYZAQ
FULYZAQ® (crofelemer) delayed-release tablets should not be used for the treatment of infectious diarrhea. It is important that your healthcare provider considers infectious causes of diarrhea before you start taking FULYZAQ. If infectious causes are not considered, and you begin taking FULYZAQ based on a probable diagnosis of noninfectious diarrhea, there is a risk that you will not receive the appropriate treatments, and your disease may worsen. • FULYZAQ tablets should be swallowed whole. FULYZAQ tablets should not be crushed or chewed. You may take FULYZAQ with or without food. You should follow the instructions of your healthcare provider. • If you are pregnant, or planning to become pregnant, talk to your healthcare provider before taking FULYZAQ. The safety and effectiveness of FULYZAQ have not been established in people younger than 18 years of age. • In clinical studies, the most common adverse reactions associated with FULYZAQ – occurring in at least 3% of patients taking FULYZAQ – were upper respiratory tract infection, bronchitis (inflammation of the lining of the tubes which carry air to and from your lungs), cough, flatulence (intestinal gas passed through your rectum), and increased bilirubin (a waste product of the breakdown of red blood cells). • You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch/ or call 1-800-FDA-1088.

Please see following page for brief summary of Prescribing Information for FULYZAQ.

Fulyzaq®
(crofelemer) 125 MG DELAYED-RELEASE TABLETS

Snap a picture of our logo and show your doctor to 'Start the Conversation'

Fulyzaq®

(crofelemer) 125 MG DELAYED-RELEASE TABLETS

IMPORTANT PATIENT INFORMATION

The following is a brief summary only. See complete Prescribing Information at Fulyzaq.com or request complete Prescribing Information by calling 1-800-508-0024. This information does not take the place of talking with your doctor about your medical condition or your treatment.

WHAT IS FULYZAQ?

FULYZAQ is a prescription medication used to improve symptoms of noninfectious diarrhea (diarrhea not caused by a bacterial, viral, or parasitic infection) in adult patients with HIV/AIDS who take HIV medication.

WHO SHOULD NOT TAKE FULYZAQ?

- FULYZAQ should not be taken if you have diarrhea caused by an infection
- Your doctor and you should make sure your diarrhea is not caused by an infection (such as bacteria, virus, or parasite) before you start taking FULYZAQ

WHAT ARE THE POSSIBLE SIDE EFFECTS OF FULYZAQ?

- Upper respiratory tract infection (nasal or sinus infection)
- Bronchitis (inflammation of the lining of the tubes which carry air to and from your lungs)
- Cough
- Flatulence (intestinal gas passed through your rectum)
- Increased bilirubin (a waste product of the breakdown of red blood cells)

For a full list of side effects, please talk to your doctor.

Tell your doctor if you have any side effect that bothers you or does not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

SHOULD I TAKE FULYZAQ IF I AM:

Pregnant or Planning to Become Pregnant?

- Studies in animals show that FULYZAQ could cause harm to an unborn baby or affect the ability to become pregnant
- There are no studies in pregnant women taking FULYZAQ
- This drug should only be used during pregnancy if clearly needed

A Nursing Mother?

- It is not known whether FULYZAQ is passed through human breast milk
- If you are nursing, you should tell your doctor before starting FULYZAQ
- Your doctor will help you to make a decision whether to stop nursing or to stop taking FULYZAQ

Under 18 or Over 65 Years of Age?

- FULYZAQ has not been studied in children under 18 years of age
- FULYZAQ studies did not contain a large number of patients over the age of 65; therefore, it is unclear if this age group will respond differently

Talk to your doctor to find out if FULYZAQ is right for you.

HOW SHOULD I TAKE FULYZAQ?

- FULYZAQ should be taken orally, by mouth 2 times per day
- FULYZAQ tablets may be taken with or without food
- FULYZAQ tablets should not be crushed or chewed
- FULYZAQ tablets should be swallowed whole

WHAT SHOULD I KNOW ABOUT TAKING FULYZAQ WITH OTHER MEDICATIONS?

- If you are taking any prescription or over-the-counter (OTC) medications, or herbal supplements or vitamins, tell your doctor before starting FULYZAQ

WHAT IF I HAVE MORE QUESTIONS ABOUT FULYZAQ?

- For more information, please see the full Prescribing Information at **Fulyzaq.com** or speak to your doctor or pharmacist

To report side effects, a product complaint, or for additional information, call: 1-800-508-0024.

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The botanical drug substance of FULYZAQ is extracted from *Croton lechleri* (the botanical raw material) that is harvested from the wild in South America.

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WOMEN PLAYED A KEY ROLE AND WERE A FOCUS OF THE CONFERENCE.

PHOTO: RODGER BOSCH

INTEGRATING PREVENTION STRATEGIES

BY JESSICA TERLIKOWSKI

October marked the first time multiple facets of the biomedical HIV prevention research field came together under a single banner, called the **HIV Research for Prevention conference** (HIVR4P). Previously the microbicide and vaccine communities operated in separate spheres with separate conferences. As the lines between interventions become less defined, this new integrated approach is an important one for the overall field of new prevention technologies.

This new collaborative approach underscores the fact that no single intervention will answer our prevention prayers. Instead, we must examine the range of options in the ever-evolving prevention landscape. This combined conference is an important first step to realizing the potential for increased collaboration.

HIVR4P brought more than 1,300 scientists, policymakers, funders, and advocates to Cape Town, South Africa, to share the latest in prevention technology research and implementation. While the topics related to biomedical prevention were diverse, common to many of them was the understanding that **effective HIV prevention requires more than just an effective product**. Effective drug formulations and acceptable delivery mechanisms are just pieces of the larger puzzle of successful HIV prevention.

We need a clear understanding of all the factors related to the social, cultural, economic, political, and physical contexts that influence a person's HIV vulnerability. Such factors are not singular in nature, but work together to reduce or increase a person's chances of becoming HIV-positive. They also play directly into each community's response to the epidemic, including the types of prevention and care services that are provided, and to whom.

For instance, social and cultural factors shaped women's decision-making when choosing whether to use the vaginal gel and tablet for prevention of HIV as instructed. They also informed how, if, and when individuals would come out as PrEP (pre-exposure prophylaxis) users to their friends, colleagues, and community members, while the political, economic, and regulatory environments determined individuals' ability to access PrEP in the first place.

What follows is a snapshot of the discussions at HIVR4P regarding how some of the factors mentioned above influenced the behaviors of study participants, and ultimately trial outcomes.

UNDERSTANDING WOMEN'S DECISIONS

Multiple sessions were dedicated to analyses of the VOICE study and shed light on the varied reasons why women did not use the test products provided while reporting that they did. Conducted by the Microbicides Trials Network (MTN), the VOICE (Vaginal and Oral Interventions to Control the Epidemic) study evaluated the safety and efficacy of daily use of oral tenofovir, oral Truvada, or a tenofovir-based vaginal gel for prevention of HIV. Trial results released in early

2013 revealed that the majority of study participants did not take the pills or use the gels as instructed, but self-reported high levels of adherence all the same. To try to understand this discrepancy, study staff conducted in-depth interviews as well as focus groups with a subset of VOICE participants.

A number of women noted that participant conversations in site waiting rooms included rumors that the study drug caused serious side effects and even HIV. Some women also feared that the gel could cause uterine cancer or negatively impact their ability to conceive. Distrust of clinic staff and negative perspectives of women's partners, family, and friends also influenced their product use. One woman whose partner did not like the product shared that her economic dependence on her partner required her to stop using it. She stated that she "had to be more obedient to him than to the clinic."

Women who were more adherent to the gel and tablets said they valued the information and guidance given by clinic staff. Having the ability to regularly access health care and discuss their sexual health, receive risk reduction counseling, and obtain condoms, HIV tests, and STI screenings was also important to them. Strategies used to overcome challenges included combatting disapproval of product use by those close to them.

These **conversations are critical to understanding women's concerns and contexts**. Such understanding can help inform the development of products and programming that meet diverse prevention needs.

A session discussing VOICE participants' understanding of anal sex was particularly intriguing. Researchers interviewed women to learn more about any anal intercourse that took place during the study. The interviews revealed that terms used in earlier questions to assess anal sex activity were not understood by all of the study participants. For example, many women interpreted anal sex to mean "vaginal sex from behind," which appeared to cause higher reporting of anal intercourse than actually occurred. And because language used to describe sex is, as the presenting researcher noted, "frequently ambiguous, indirect, and euphemistic," collecting accurate data through non-conversational self-reports can result in misinterpretation of questions asked and answers given.

Another study sought to understand women's decisions to stop taking PrEP. Reasons given included a partner's absence, or lack of a partner. Others stated they would stop taking PrEP if a partner asked them to stop, raising the issue again of how a myriad of factors, particularly relationship dynamics, influence a woman's decision to use any prevention option, even one that can be taken without her partner's knowledge. Pregnancy, side effects, and disruption of routine due to travel were also named as reasons why they might choose to press pause on PrEP use. And again, issues that are determined by political and economic realities also loomed large in deciding to PrEP or not to PrEP. Women stated that if accessibility, availability, and affordability prohibited use, then they should stop their PrEP use.

Also presented at HIVR4P was another effort to understand women's decision-making regarding communicating product use. Researchers asked the participants of the CAPRISA trial to whom and when they disclosed product use. (CAPRISA found that using a tenofovir microbicide gel before and after vaginal sex reduced women's risk of HIV by 39%. Stay tuned for FACTS trial data due out this year, seeking to confirm the CAPRISA efficacy data.)

Researchers also conducted focus groups and in-depth interviews with partners of women enrolled in the study, as well as men in the community who were not partners of study participants. Outcomes indicated that women were more likely to share that they were using the product with partners they felt positively towards. In other words, the more negative the feelings toward a partner, the less likely a woman was to share that she was using a microbicide. Disclosure was a process for the women and contingent upon the relationship with partners and other circumstances. Similarly, their male partners' acceptance of women's product use also took time. When asked their thoughts about disclosing product use, men who did not have partners on the gel reported that communicating product use indicated a relationship's stability and respect for autonomous decision-making.

PrEP ACCESS

The United States is the only country where Truvada is approved for PrEP. Consequently, communities vulnerable to HIV, including thousands of **study participants outside the U.S. who made the PrEP findings possible, are unable to access it**. Instead, these individuals can only (potentially) access PrEP through off-label prescriptions, demonstration projects, and open-label studies. In the case of PrEP studies TDF2 and iPrEx, study participants who previously accessed PrEP through the clinical trial faced access gaps between the end of the first study and the start of the next. Such access gaps put the health of those very individuals who made PrEP possible at risk.

Bridget Haire of the University of New South Wales Australia and the Australian Federation of AIDS Organisations noted during her plenary session that such interruptions to access must and can be prevented. She called for ensuring that clinical trial designs include plans to ensure continuous drug delivery following a trial's end. Identifying the steps and systems that are necessary for ongoing access during the trial's front end will make it possible for those participants who want continued product access to obtain it. The need for such intentionality in trial design is not unique to PrEP. It is necessary for any and all of the new prevention technologies that are in development.

SO WHAT DO WE DO NOW?

Well, the Mapping Pathways project housed at the AIDS Foundation of Chicago (AFC) has a few ideas. (Full disclosure, I work on this project and had a poster on it at HIVR4P.) The project is all about the need to **identify and consider community-specific factors beyond**

clinical data that determine successful implementation of antiretroviral-based prevention options including PrEP, PEP (post-exposure prophylaxis), treatment, and microbicides. These factors are political, economic, social, and cultural. And they must be examined and understood in the clinical trial context if we are to understand what must be done to ensure that the people who need new prevention options can both access and use them.

Understanding these factors and integrating that understanding into the design of clinical trials, behavioral research, and implementation programs is essential for the success of any prevention technology. It simply is not enough to know that a product is safe, acceptable, and effective. We must also know what type of policy and economic environment will foster its availability. We must engage diverse stakeholders to enable uptake. We must listen to the community that these products are being designed for and authentically involve them in every aspect from development to implementation to evaluation—so the field develops things that people want. We must honor their contributions and not discount their experiences.

Chicago will host the next HIVR4P in October 2016. Stay tuned.

JESSICA TERLIKOWSKI is Director of Prevention Technology Education at the AIDS Foundation of Chicago. Go to aidschicago.org.

FOR WEBCASTS, PRESENTATIONS, AND POSTERS FROM THE CONFERENCE. GO TO HIVR4P.ORG.

PHOTO: RODGER BOSCH

PrEP TALK: ADVOCATES SHARED THEIR EXPERIENCES ON A PANEL MODERATED BY ANNA FORBES (RIGHT).

PERSPECTIVES ON PrEP

The most compelling part of the HIVR4P conference was a session at the Advocates Pre-Conference that provided a platform for PrEP users from four different countries to share their experiences and perspectives. The panelists included three gay men from South Africa, Canada, and France and one young female sex worker from Zimbabwe. Each person **shared their very personal reasons for choosing to use PrEP and what that decision means for them**. They eloquently articulated why HIV researchers, prevention advocates, program implementers, and funders must understand the complex factors that determine successful implementation of these new strategies, as well as continue to provide "more mechanisms for prevention."

Marc-André of Canada, a long-time HIV prevention advocate, gave a moving account of just how powerful PrEP is on a person's psyche. Visibly emotional, he shared that he has undergone a transformative experience because his anxiety related to HIV risk is so significantly reduced. His honesty and emotion underscored what is too frequently understated in PrEP discussions. PrEP gives people peace of mind. Since going on PrEP, Marc-André has used his personal story in his writing and advocacy to reduce PrEP stigma. His candor has proven effective. Upon learning he is on PrEP, his PrEP-averse friends are re-examining this option and their views about it.

Emanuel of France spoke to his concerns of being judged by his friends, "When I started two years ago I didn't tell anybody. I knew I would be shamed because it means that I didn't use condoms all of the time." However, when he finally decided to share with his friends that he was on PrEP, he did not experience any condemnation.

Bathabile, the Zimbabwean sex worker, said, "There are so many chances when I am vulnerable to HIV. I have to protect myself with those things. PrEP makes me feel like I am in control. It makes me feel empowered." While noting that her friends understood her decision to go on PrEP because they are in the same industry, she stated that she is stigmatized, as is sex work, by those who should be on her side and lending her support. She cited being discriminated against by other women. But she is undeterred. "I do it [PrEP] for myself and my health."

As advocates for HIV prevention, social justice, and sexual health, it is incumbent upon us to advance an agenda that respects individuals' ability to take control of their health.

One Advocates Pre-Conference participant summarized the power of these personal stories by saying, "Once it is personal, it makes sense." Another issued a call to action by saying that, "Community has a responsibility to get policymakers to make the right decisions to get people what they need."

—JESSICA TERLIKOWSKI

AGING GRACIE-FULLY

FACING THE CHALLENGES OF GROWING OLDER WITH HIV AS A COMMUNITY

BY RICK LOFTUS, MD

PHOTO: THINKSTOCK.COM

They say it takes a village to raise a child. I would also say: It takes a village to support an elder.

I made this remark at a lecture on HIV and aging that I gave in New Orleans last year, sponsored by Merck, in conjunction with the United States Conference on AIDS. The audience consisted of about a hundred AIDS care professionals, mostly physicians, nurse practitioners, and pharmacists, in addition to case managers and patient educators.

I have to confess that I somewhat dread lectures on HIV and aging—both hearing them and giving them. In the past few years, those of us working in HIV care and research and our patients have spent increasing amounts of time talking about this subject. Every time you turn around, it seems, there's another lecture or webinar about it, almost to the point I feel we hardly talk about anything else anymore.

On one hand, it's a definite privilege that we get to worry about aging with HIV, given where we were even 15 years ago. That doesn't allay our simultaneous concerns, however, about the special challenges we'll confront as adults living with HIV enter their "golden years." Maintaining the health and good function of aging adults—*all* adults—is a topic of active study, and we've barely begun to understand it. That goes double for the special case of adults also burdened with chronic HIV infection.

WORKING TOGETHER

Those of us working as health care providers of adults already can see over the horizon the "grey tsunami" approaching, as the Baby Boomer generation gets within a hand's reach of age 70 and beyond. We worry about the declining ability of our patients to care for themselves, and we worry about our ability to anticipate problems for these patients well enough to prevent medical catastrophe.

I would say, however, that as a former ACT UP'er who later became an AIDS researcher and HIV physician, my experience when facing seemingly overwhelming or unsolvable problems is that what seems impossible when faced alone becomes possible when faced with a community at your back. Much of what the AIDS community has accomplished in our 30-plus year history seems in hindsight quite remarkable.

Activists dispatched problems of medicine, science, and policy again and again, working together. I remain optimistic that this same approach will pay off in meeting the latest set of challenges of aging HIV-positive adults, and this is the message I have strived to bring to audiences when I speak on the topic.

The generalities of the issue of HIV and aging came into sharp personal focus for me in the past five years, as I now live in the retirement community of the Coachella Valley, in Southern California. I work in a large medical group practice in Palm Springs, and my particular office caters mainly to the aging LGBT patient population, many of whom are also living with HIV.

I came to the valley almost five years ago to take a job helping create a new internal medicine residency at Eisenhower Medical Center. Eisenhower is one of the two largest hospitals in the region and the first to have any kind of academic medicine program. That, too, has brought with it its own set of challenges. But it did not take long for me to realize the special opportunities such a place offers to medical researchers interested in the problems of "successful aging"—again, both in the general adult population and in those living with HIV.

In the article below, I will outline the nature of the problem posed by aging successfully with HIV, and then talk about how I and my research collaborators here in the Coachella Valley are taking advantage of the increasing numbers of HIV-positive adults living in the area to launch a project aimed at gaining insight into their special needs. Our hope, of course, is that the lessons we learn will assist service agencies and policy makers worldwide in better addressing the needs of our patient community.

HIV AND AGING: THE SCOPE OF THE PROBLEM

"I have to deal with the reality."

–PROJECT GRACIE FOCUS GROUP PARTICIPANT

In the developed world, the face of HIV infection is growing older. Most of us have heard the statistic that by 2015, 50% of all HIV-positive adults in the U.S. will be over the age of 50. Going along with this trend, HIV patients today are not only living with HIV, but with the "diseases of aging." As people with HIV enter their 60s, more than half of them will demonstrate hypertension and high cholesterol. Nearly 20% will have documented coronary artery disease, the condition that gives rise to heart attacks; over 25% will have kidney disease and a similar number will have confirmed diabetes.

There are some special issues with HIV-positive adults dealing with other chronic medical conditions. For one, compared to their HIV-negative peers, adults living with HIV seem to be more likely to be dealing with more than one chronic medical condition at a time. In one study in veterans, for example, people living with HIV who were 50 years of age or older were much more likely to have multiple other chronic illnesses compared with their age-matched HIV-negative peers. For adults with HIV age 60 or older, the vast majority—70%—had at least one other chronic medical problem. Coronary artery disease, at least until people reach their 70s, seems to be roughly three times more prevalent in HIV-positive adults compared to HIV-negative people of the same age, even when corrected for the presence of other risk factors such as smoking or obesity.

Besides the high rate of kidney disease previously mentioned, patients also have a high rate of liver disease—often due to co-infection with hepatitis B or hepatitis C. Rates of bone density loss—osteopenia and osteoporosis—are much higher in HIV-positive adults when compared to HIV negative adults, and unsurprisingly, the rate of bone fractures is 50% higher.

Perhaps most worrisome to my audiences of HIV-positive adults is the higher rate of memory impairment and development of early dementia we are seeing. Even HIV-positive adults with no other HIV-related symptoms will more commonly experience a decline in brain function. One study found that the rate is nearly twice as high, with at least mild cognitive impairment—problems with thinking or memory—being found in 36% of HIV-positive adults, compared with 16% in HIV-negative people of the same age.

The neurocognitive issues of HIV-infected adults is a special research interest of our collaborators from UC San Diego, Drs. Ronald Ellis and David Moore, and we have been assisting them in reaching more elderly HIV-positive adults living in the valley for their important work in this area.

Not only do people with HIV contend with more medical problems compared to their HIV-negative peers, they also seem to have a rougher time with the conditions they do have. One of the most striking studies speaking to this was conducted by Kris Ann Oursler, a gerontologist at the University of Maryland with an interest in HIV-positive adults. Her project, analyzing health outcomes in veterans, found that patients' function in daily activities, as assessed by patients themselves, declined three times faster in HIV-positive adults compared to their HIV-negative peers *living with the same conditions*.

For example, for a person who had chronic obstructive lung disease (COPD, sometimes known to laypersons as "smoker's lungs"), his or her ability to manage daily tasks affected by that condition, such as limited walking due to shortness of breath, got worse over time at a faster rate if the person also had HIV infection.

CAUSES

What drives the higher number and severity of chronic medical conditions in HIV-positive adults? It has been hypothesized that HIV may hyper-stimulate the immune system, producing chronic inflammation. "Inflammation" is familiar to anyone who's had a splinter. The area around the splinter may get red, hot, and swollen; all of these are physical signs of an active immune system "fighting" the foreign invader—in this case, the piece of wood.

These immune activities in the short term may help fight off a challenge to the body, such as an infection. But, if inflammation persists for days, months, or years, it can take a toll on the body. Imagine you are cooking at home, and the food in the frying pan starts to burn. The smoke alarm goes off, you pull the pan off the stove, and a fire is prevented. On the other hand, if the smoke alarm never shuts off, it would really start to make the cook feel frazzled. Like a smoke alarm that won't shut up, inflammation that never shuts off can turn from the body's friend into its foe.

One important study that gave us insight into the chronic inflammation of HIV-infection was the SMART study, which looked at HIV-positive adults using HIV medications. The study compared patients who stayed on their medicines consistently to those who took breaks from their medicines from time to time (what we call "drug holidays" or "treatment interruptions"). The big lesson of the study was that taking breaks from medication actually produced much

worse outcomes for the patients than staying on medicines consistently from day to day.

In the SMART study, patients with HIV infection who were treated using a CD4 count-guided "drug conservation" approach had significantly greater all-cause mortality than those treated for maximal viral suppression. The role of inflammatory and coagulation biomarkers in mortality in this population has subsequently been studied.

Older adults participating in the SMART study, compared with adults from two large general population studies, had significant elevations in markers of inflammatory (hsCRP and IL-6), coagulation, and fibrinolysis activity (D-dimer), as well as renal function impairment (cystatin-C).

Besides the medical issues, there are social factors that distinguish HIV-positive adults that concern me as a primary care provider who takes care of them. I consider social isolation—living alone, and/or having fewer family or friends around to offer help when needed—to be a dangerous risk factor for poor medical outcomes in my patients, and when I see that, I try to get these patients enrolled in programs that bring volunteers or other help into the home. While it varies from person to person, the literature shows that on average, older HIV-positive adults tend to be more socially isolated than their younger counterparts. Older people with HIV are also more likely to live alone. This may also contribute to their challenges in successfully meeting the challenges of aging.

MEET GRACIE

"We are an open book."

–PROJECT GRACIE FOCUS GROUP PARTICIPANT

Southern California's Coachella Valley and Inland Empire are home to one of the largest groups of long-term survivors of HIV infection to be found anywhere in the world. As a retirement community, Palm Springs has been a traditional magnet for LGBT vacationers, and often as these adults approach retirement age, they make their stays here longer and longer until they become year-round residents. Many of these people are living with HIV.

In the past five years, the number of doctors and nurses trained in HIV care living here has greatly increased in order to meet the special needs of this group of individuals. As noted above, these patients struggle with the insidious effects of chronic HIV infection and co-morbid diseases of aging, as well as from the side effects of long-term multi-drug antiretroviral therapy.

In the past year, I and my research team, including Drs. Gerry Bocian and Carlos Martinez, and research assistant Erik Hernandez, have been meeting monthly with clinician-scientists working at other HIV care centers around the valley. Our colleagues include Dr. Clayton Barbour, nurse practitioner Joseph Dahman, and nurse Chuck Marbley, all from Borrego Community Health Foundation; Dr. Shubha Kerkar, a founding physician of the Desert AIDS Project (DAP) and main HIV provider at Desert Oasis HMO; and Dr. Steven Scheibel, the medical director of DAP. The purpose of our meetings was to discuss common concerns regarding our care and research work here.

At one of our meetings in early 2014, our aforementioned UCSD colleagues Drs. Ron Ellis and David Moore presented a summary of recent cohort studies of HIV-positive adults. They noted that the number of adults age 65 or older, in total, across about a dozen studies combined, numbered no more than about two dozen individuals. In my own panel, it is the group of adults *under* the age of 50 that I can count on two hands—most of my HIV patients are significantly older. The pattern is the same for the other local HIV providers.

After discussion, we agreed that we had a unique opportunity here—indeed, a responsibility—to take advantage of this concentration of adults aging with HIV to better understand their health and care needs. Thus, we created plans for Project GRACIE (Geriatric Research of AIDS Comorbidities in the Inland Empire), a prospective cohort study of HIV-positive adults aged 50 or older, as well as HIV-negative, aged-matched peers.

The purpose of Project GRACIE is to rectify the absence of information on HIV-positive elders and their specific aging-related challenges by enrolling up to 300 individuals, all over age 50, in a decade-long, prospective study that will provide the scientific, pharmaceutical, and medical communities with an accurate, detailed, data-rich portrait of aging AIDS patients—and provide clear guidelines for the optimal medical management of older, seropositive individuals.

Project GRACIE's approach is informed by some of the specific challenges posed by our situation in the valley—and I think our roots in the activism of the AIDS movement will help us. For starters, aside from our relationship with our colleagues at UCSD, we have no major medical university program as a base; rather, we will be doing this research work "in the community." Fortunately, the AIDS movement practically invented "community-based research," starting with the Community Research Initiative on AIDS (now known as ACRIA) in New York, co-founded by my former mentor, Dr. Joseph Sonnabend, and its San Francisco counterpart, the Community Consortium, led by another of my mentors, Dr. Donald Abrams. Both organizations pioneered the implementation of cutting-edge basic and clinical research conducted in the office of AIDS primary care providers, outside a university setting, in the early 1990s.

Community-based research doesn't simply mean doing research work outside a university. It also connotes a partnership with the patients, informed by feedback on their needs and concerns.

I am hoping, along with my Coachella Valley colleagues, to instill in our future work the same kind of partnering with patient volunteers in our research that I witnessed in many UCSF projects in San Francisco. I had the good fortune in the mid-1990s to work with Dr. Mike McCune's lab at the Gladstone Institute of Virology and Immunology (GIVI) at UCSF. There, I watched his team of scientists benefit "at the bench side" from an ongoing dialogue with patients and activists who contributed to the development of their studies and supported their success. I also helped Dr. Steven Deeks create the SCOPE cohort—now a large, NIH-supported prospective study based at San Francisco General Hospital—and watched the development of the OPTIONS early HIV infection cohort study there. Both projects exemplified similar active partnership with the patient volunteers. It was part of the work culture of the clinician-scientists at our labs to see patients as active members of the research team, contributing in the most personal way possible—with their bodies. But patients also helped by giving us their ideas, observation, and feedback, and their willingness to let their primary care providers and the larger patient community know about our work. We hope to establish a similar culture of partnership with Project GRACIE.

GRACIE UNDER PRESSURE

"Take what you need and what you want, because essentially you need this information from us."

–PROJECT GRACIE FOCUS GROUP PARTICIPANT

To get GRACIE off on the right foot, we have been conducting focus groups with HIV-positive adults age 55 or older, to get their direct feedback about what their concerns would be in participating in such a project. This will allow us to anticipate the concerns of our volunteers and address them right from the start of the project. I think we will have the support of the community.

And, we will need it. Establishing a prospective cohort study in a community setting is no mean feat. It will require significant organizational support, which translates into a need for expertise and finances. We attempt it at a time when NIH funding for *all* medical research has been declining steadily every year for the past decade. It feels like climbing a mountain.

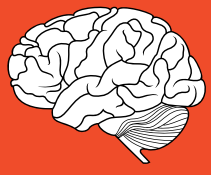
Fortunately, when one climbs Mount Everest, one goes up the icy slopes with a band of fellow mountaineers. And, with Project GRACIE, so far, every time I thought we were licked and couldn't surmount the next challenge, people came out of the woodwork to help us. We have been helped by our local activists, including Jeff Taylor and Jonathan Goldman, who've been running our focus groups; Marlene Estevez, a local pre-medical student and the main administrator of the nascent project; Edwin "Ned" Bayrd, formerly of the UCLA AIDS Institute, whose operational savvy has been hugely helpful; and many others. It is the contributions of these additional people that have allowed our science team to continue to push forward, step by step.

Funding for GRACIE will be a creative challenge. As I mentioned, NIH funding continues to drop for projects like this. We've been in touch with Dr. Kenneth Lichtenstein of the HOPS HIV cohort study—a famous study somewhat similar in nature to what we envision for GRACIE—who has given us some ideas of ways to add to our infrastructure without adding to our explicit expenses. Many of the AIDS-care and medical organizations in our region—including my own hospital—have supported their operations with private donations, and we will likely proceed in a similar fashion. Likewise, so far our GRACIE focus group participants have commented that they do not have a problem with us getting financial support from pharmaceutical industry sources, so long as the GRACIE team—researchers and participants—controls the research agenda. And, as I mentioned, all of what we've accomplished to date has happened thanks to volunteers.

70%
OF HIV-POSITIVE ADULTS AGE 60 OR OLDER HAD AT LEAST ONE OTHER CHRONIC MEDICAL PROBLEM.

RATES OF BONE DENSITY LOSS ARE MUCH HIGHER. THE RATE OF BONE FRACTURES IS

50% HIGHER



36%
OF HIV-POSITIVE OLDER ADULTS WERE FOUND TO HAVE SOME LEVEL OF **COGNITIVE IMPAIRMENT**—PROBLEMS WITH THINKING OR MEMORY—COMPARED TO 16% IN HIV-NEGATIVE PEOPLE OF THE SAME AGE.

GRACIE: NEXT STEPS

"It would be nice to be asked if I need to talk to someone. A lot of these trials bring up emotional history."

–PROJECT GRACIE FOCUS GROUP PARTICIPANT

The next step in our work—what we've dubbed "Phase 0"—will be a planned chart review project, which will be handled by a four-person team of resident doctors, working under each of our principal investigators at their individual clinic locations. The purpose of this phase will be to characterize the comorbid medical problems of older HIV patients, and compare those findings to the established medical literature. This part was formally announced December 1, 2014, World AIDS Day. The nice part about a chart review project is that its financial burdens are quite modest.

The next phase would include, in addition to surveys of the patient-participants, collecting and storing blood and tissue samples taken from volunteers. The objective of this phase of Project GRACIE will be to monitor, quantify, and compare the comorbidities seen in older individuals living with HIV to those in age-matched sero-negative controls. A number of clinical markers of disease, including some of the inflammatory markers mentioned above, will be monitored in this work.

It has been interesting to me that the focus group members have commented that getting support for coping with the challenges of aging doesn't simply mean studying the problems. While they recognize the need to involve the pharmaceutical industry as partners in supporting this work, they also wanted to make sure the investigators think about complementary therapies, including nutrition and modalities like acupuncture, in the therapeutic studies that will likely unfold out of the GRACIE project. Likewise, I anticipate that GRACIE will partner with some of our local care agencies to make sure our participants will take advantage of the existing support resources in the valley, even as our research helps shape and mold those resources for even better support in the future.

So, it takes a village. In surmounting the challenges of AIDS, it always has, and probably always will. Project GRACIE will move forward thanks to the support of many scientists, care providers, and advocates, but most importantly, the community of aging HIV-positive adults living here in the valley. I hope what we learn will benefit the larger world community of people living with HIV/AIDS and care providers. PA

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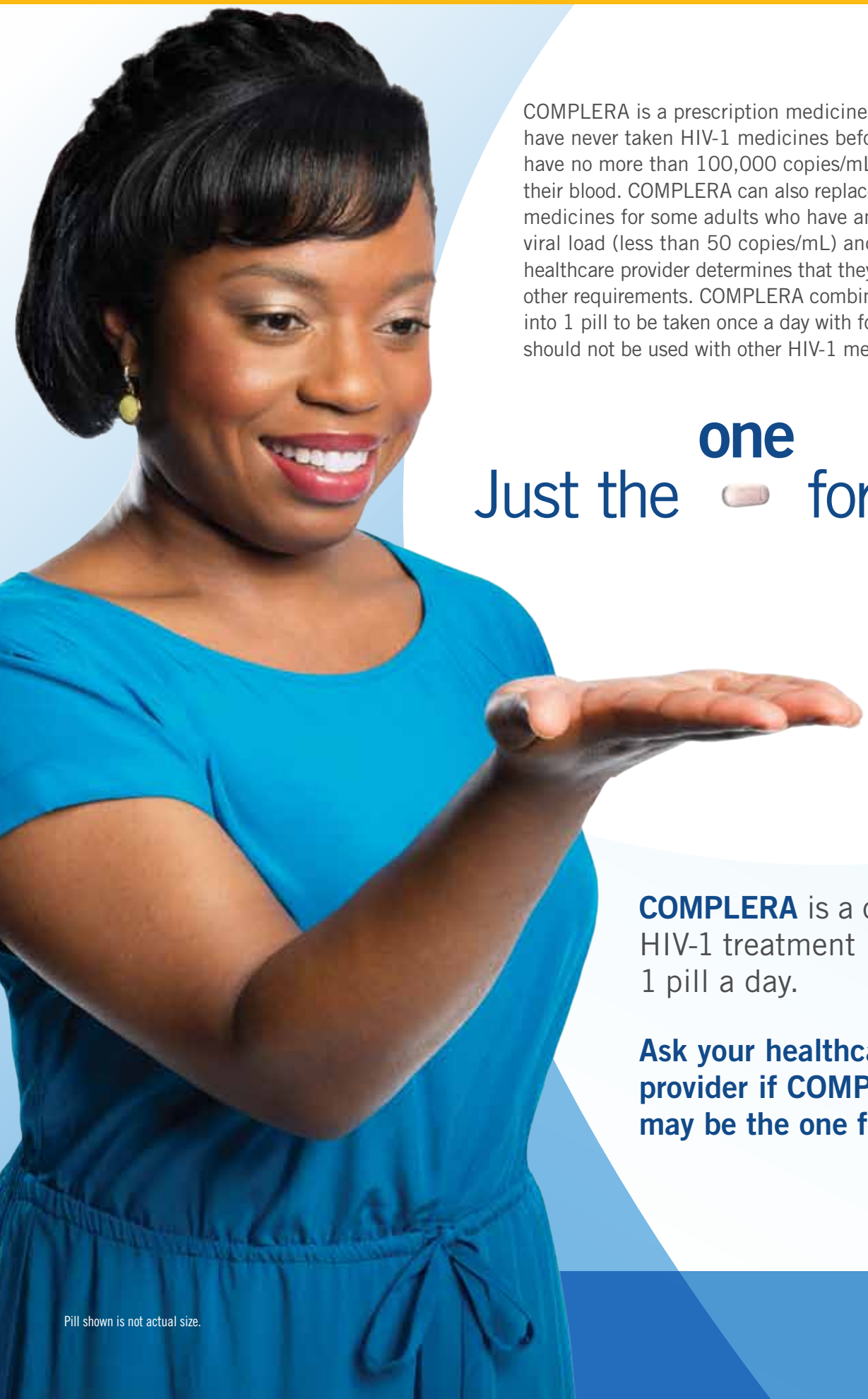

COMPLERA is a prescription medicine for adults who have never taken HIV-1 medicines before and who have no more than 100,000 copies/mL of virus in their blood. COMPLERA can also replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL) and whose healthcare provider determines that they meet certain other requirements. COMPLERA combines 3 medicines into 1 pill to be taken once a day with food. COMPLERA should not be used with other HIV-1 medicines.

Just the one for me

COMPLERA is a complete HIV-1 treatment in only 1 pill a day.

Ask your healthcare provider if COMPLERA may be the one for you.

Pill shown is not actual size.

COMPLERA does not cure HIV-1 infection or AIDS.

To control HIV-1 infection and decrease HIV-related illnesses you must keep taking COMPLERA. Ask your healthcare provider if you have questions about how to reduce the risk of passing HIV-1 to others. Always practice safer sex and use condoms to lower the chance of sexual contact with body fluids. Never reuse or share needles or other items that have body fluids on them.

It is not known if COMPLERA is safe and effective in children under 18 years old.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about COMPLERA?

COMPLERA can cause serious side effects:

- **Build-up of an acid in your blood (lactic acidosis),** which is a serious medical emergency. Symptoms of lactic acidosis include feeling very weak or tired, unusual (not normal) muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold especially in your arms and legs, feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.
- **Serious liver problems.** The liver may become large (hepatomegaly) and fatty (steatosis). Symptoms of liver problems include your skin or the white part of your eyes turns yellow (jaundice), dark "tea-colored" urine, light-colored bowel movements (stools), loss of appetite for several days or longer, nausea, and/or stomach pain.
- **You may be more likely to get lactic acidosis or serious liver problems** if you are female, very overweight (obese), or have been taking COMPLERA for a long time. In some cases, these serious conditions have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.
- **Worsening of hepatitis B (HBV) infection.** If you also have HBV and stop taking COMPLERA, your hepatitis may suddenly get worse. Do not stop taking COMPLERA without first talking to your healthcare provider, as they will need to monitor your health. COMPLERA is not approved for the treatment of HBV.

Who should not take COMPLERA?

Do not take COMPLERA if you:

- **Take a medicine that contains:** adefovir (Hepsera), lamivudine (Epivir-HBV), carbamazepine (Carbatrol, Equetro, Tegretol, Tegretol-XR, Teril, Epitol), oxcarbazepine (Trileptal), phenobarbital (Luminal), phenytoin (Dilantin, Dilantin-125, Phenytek), rifampin (Rifater, Rifamate, Rimactane, Rifadin), rifapentine (Priftin), dexlansoprazole (Dexilant), esomeprazole (Nexium, Vimovo), lansoprazole (Prevacid), omeprazole (Prilosec, Zegerid), pantoprazole sodium (Protonix), rabeprazole (Aciphex), more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate, or the herbal supplement St. John's wort.
- **Take any other medicines to treat HIV-1 infection,** unless recommended by your healthcare provider.

What are the other possible side effects of COMPLERA?

Serious side effects of COMPLERA may also include:

- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood tests to check your kidneys before starting treatment with COMPLERA. If you have had kidney problems, or take other medicines that may cause kidney problems, your healthcare provider may also check your kidneys during treatment with COMPLERA.
- **Depression or mood changes.** Tell your healthcare provider right away if you have any of the following symptoms: feeling sad or hopeless, feeling anxious or restless, have thoughts of hurting yourself (suicide) or have tried to hurt yourself.
- **Changes in liver enzymes:** People who have had hepatitis B or C, or who have had changes in their liver function tests in the past may have an increased risk for liver problems while taking COMPLERA. Some people without prior liver disease may also be at risk. Your healthcare provider may do tests to check your liver enzymes before and during treatment with COMPLERA.
- **Bone problems,** including bone pain or bones getting soft or thin, which may lead to fractures. Your healthcare provider may do tests to check your bones.
- **Changes in body fat** can happen in people taking HIV-1 medicines.
- **Changes in your immune system.** Your immune system may get stronger and begin to fight infections. Tell your healthcare provider if you have any new symptoms after you start taking COMPLERA.

The most common side effects of COMPLERA include trouble sleeping (insomnia), abnormal dreams, headache, dizziness, diarrhea, nausea, rash, tiredness, and depression. Other common side effects include vomiting, stomach pain or discomfort, skin discoloration (small spots or freckles), and pain. Tell your healthcare provider if you have any side effects that bother you or do not go away.

What should I tell my healthcare provider before taking COMPLERA?

- **All your health problems.** Be sure to tell your healthcare provider if you have or had any kidney, mental health, bone, or liver problems, including hepatitis virus infection.
- **All the medicines you take,** including prescription and nonprescription medicines, vitamins, and herbal supplements. COMPLERA may affect the way other medicines work, and other medicines may affect how COMPLERA works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Do not start any new medicines while taking COMPLERA without first talking with your healthcare provider.
- **If you take rifabutin (Mycobutin).** Talk to your healthcare provider about the right amount of rilpivirine (Edurant) you should take.
- **If you take antacids.** Take antacids at least 2 hours before or at least 4 hours after you take COMPLERA.
- **If you take stomach acid blockers.** Take acid blockers at least 12 hours before or at least 4 hours after you take COMPLERA. Ask your healthcare provider if your acid blocker is okay to take, as some acid blockers should never be taken with COMPLERA.
- **If you are pregnant** or plan to become pregnant. It is not known if COMPLERA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking COMPLERA.
- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk. Also, some medicines in COMPLERA can pass into breast milk, and it is not known if this can harm the baby.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Brief Summary of full Prescribing Information with **important warnings** on the following pages.

COMPLERA®
emtricitabine 200mg/rilpivirine 25mg/
tenofovir disoproxil fumarate 300mg tablets

GILEAD

Brief Summary of full Prescribing Information

COMPLERA® (kom-PLEH-rah)

(emtricitabine 200 mg, rilpivirine 25 mg, tenofovir disoproxil fumarate 300 mg) tablets

Brief summary of full Prescribing Information. For more information, please see the full Prescribing Information, including Patient Information.

What is COMPLERA?

- **COMPLERA** is a prescription medicine used as a complete HIV-1 treatment in one pill a day. COMPLERA is for adults who have never taken HIV-1 medicines before and who have no more than 100,000 copies/mL of virus in their blood (this is called 'viral load'). Complera can also replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL) and whose healthcare provider determines that they meet certain other requirements.
- COMPLERA is a complete regimen and should not be used with other HIV-1 medicines. HIV-1 is the virus that causes AIDS. When used properly, COMPLERA may reduce the amount of HIV-1 virus in your blood and increase the amount of CD4 T-cells, which may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak.
- **COMPLERA does not cure HIV-1 or AIDS.** You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.
- **Ask your healthcare provider about how to prevent passing HIV-1 to others.** Do not share or reuse needles, injection equipment, or personal items that can have blood or body fluids on them. Do not have sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

What is the most important information I should know about COMPLERA?

COMPLERA can cause serious side effects, including:

- **Build-up of an acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take COMPLERA or similar (nucleoside analogs) medicines. Lactic acidosis is a serious medical emergency that can lead to death. Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. **Call your healthcare provider right away if you get any of the following symptoms which could be signs of lactic acidosis:**
  - feel very weak or tired
  - have unusual (not normal) muscle pain
  - have trouble breathing
  - having stomach pain with nausea or vomiting
  - feel cold, especially in your arms and legs
  - feel dizzy or lightheaded
  - have a fast or irregular heartbeat
- **Severe liver problems.** Severe liver problems can happen in people who take COMPLERA. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Call your healthcare provider right away if you get any of the following symptoms of liver problems:**
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark "tea-colored" urine
  - light-colored bowel movements (stools)
  - loss of appetite for several days or longer
  - nausea
  - stomach pain
- **You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking COMPLERA for a long time.**
- **Worsening of Hepatitis B infection.** If you have hepatitis B virus (HBV) infection and take COMPLERA, your HBV may get worse (flare-up) if you stop taking COMPLERA. A "flare-up" is when your HBV infection suddenly returns in a worse way than before. COMPLERA is not approved for the treatment of HBV, so you must discuss your HBV with your healthcare provider.
  - Do not run out of COMPLERA. Refill your prescription or talk to your healthcare provider before your COMPLERA is all gone.
  - Do not stop taking COMPLERA without first talking to your healthcare provider.
  - If you stop taking COMPLERA, your healthcare provider will need to check your health often and do blood tests regularly to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking COMPLERA.

Who should not take COMPLERA?

Do not take COMPLERA if you also take any of the following medicines:

- **Medicines used for seizures:** carbamazepine (Carbatrol, Equetro, Tegretol, Tegretol-XR, Teril, Epitol); oxcarbazepine (Trileptal); phenobarbital (Luminal); phenytoin (Dilantin, Dilantin-125, Phenytek)
- **Medicines used for tuberculosis:** rifampin (Rifater, Rifamate, Rimactane, Rifadin); rifapentine (Priftin)
- **Certain medicines used to block stomach acid called proton pump inhibitors (PPIs):** dexlansoprazole (Dexilant); esomeprazole (Nexium, Vimovo); lansoprazole (Prevacid); omeprazole (Prilosec, Zegerid); pantoprazole sodium (Protonix); rabeprazole (Aciphex)
- **Certain steroid medicines:** More than 1 dose of dexamethasone or dexamethasone sodium phosphate
- **Certain herbal supplements:** St. John's wort
- **Certain hepatitis medicines:** adefovir (Hepsera), lamivudine (Epivir-HBV)

Do not take COMPLERA if you also take any other HIV-1 medicines, including:

- Other medicines that contain tenofovir (ATRIPLA, STRIBILD, TRUVADA, VIREAD)
- Other medicines that contain emtricitabine or lamivudine (ATRIPLA, Combivir, EMTRIVA, Epivir, Epzicom, STRIBILD, Trizivir, TRUVADA)
- rilpivirine (Edurant), unless you are also taking rifabutin (Mycobutin)

COMPLERA is not for use in people who are less than 18 years old.

What are the possible side effects of COMPLERA?

COMPLERA may cause the following serious side effects:

- **See "What is the most important information I should know about COMPLERA?"**
- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking COMPLERA. If you have had kidney problems in the past or need to take another medicine that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with COMPLERA.
- **Depression or mood changes. Tell your healthcare provider right away if you have any of the following symptoms:**
  - feeling sad or hopeless
  - feeling anxious or restless
  - have thoughts of hurting yourself (suicide) or have tried to hurt yourself
- **Change in liver enzymes.** People with a history of hepatitis B or C virus infection or who have certain liver enzyme changes may have an

increased risk of developing new or worsening liver problems during treatment with COMPLERA. Liver problems can also happen during treatment with COMPLERA in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with COMPLERA.

- **Bone problems** can happen in some people who take COMPLERA. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.
- **Changes in body fat** can happen in people taking HIV-1 medicine. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effect of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having any new symptoms after starting your HIV-1 medicine.

The most common side effects of COMPLERA include:

- Trouble sleeping (insomnia), abnormal dreams, headache, dizziness, diarrhea, nausea, rash, tiredness, depression

Additional common side effects include:

- Vomiting, stomach pain or discomfort, skin discoloration (small spots or freckles), pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

- These are not all the possible side effects of COMPLERA. For more information, ask your healthcare provider.
- Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I tell my healthcare provider before taking COMPLERA?

Tell your healthcare provider about all your medical conditions, including:

- If you have or had any kidney, mental health, bone, or liver problems, including hepatitis B or C infection.
- If you are pregnant or plan to become pregnant. It is not known if COMPLERA can harm your unborn child.
  - There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you take COMPLERA.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - Two of the medicines in COMPLERA can pass to your baby in your breast milk. It is not known if this could harm your baby.
  - Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements:

- COMPLERA may affect the way other medicines work, and other medicines may affect how COMPLERA works.
- If you take certain medicines with COMPLERA, the amount of COMPLERA in your body may be too low and it may not work to help control your HIV-1 infection. The HIV-1 virus in your body may become resistant to COMPLERA or other HIV-1 medicines that are like it.
- Be sure to tell your healthcare provider if you take any of the following medicines:
  - Rifabutin (Mycobutin), a medicine to treat some bacterial infections. Talk to your healthcare provider about the right amount of rilpivirine (Edurant) you should take.
  - Antacid medicines that contain aluminum, magnesium hydroxide, or calcium carbonate. Take antacids **at least 2 hours before or at least 4 hours after** you take COMPLERA.
  - Certain medicines to block the acid in your stomach, including cimetidine (Tagamet), famotidine (Pepcid), nizatidine (Axid), or ranitidine hydrochloride (Zantac). Take the acid blocker **at least 12 hours before or at least 4 hours after** you take COMPLERA. Some acid blocking medicines should never be taken with COMPLERA (see "Who should not take COMPLERA?" for a list of these medicines).
  - Medicines that can affect how your kidneys work, including acyclovir (Zovirax), cidofovir (Vistide), ganciclovir (Cytovene IV, Vitrasert), valacyclovir (Valtrex), and valganciclovir (Valcyte).
  - clarithromycin (Biaxin)
  - erythromycin (E-Mycin, Eryc, Ery-Tab, PCE, Pediazole, Ilosone)
  - fluconazole (Diflucan)
  - itraconazole (Sporanox)
  - ketoconazole (Nizoral)
  - methadone (Dolophine)
  - posaconazole (Noxafil)
  - telithromycin (Ketek)
  - voriconazole (Vfend)

Know the medicines you take. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. Do not start any new medicines while you are taking COMPLERA without first talking with your healthcare provider.

How should I take COMPLERA?

- Stay under the care of your healthcare provider during treatment with COMPLERA.
- Take COMPLERA exactly as your healthcare provider tells you to take it.
- Always take COMPLERA with food. Taking COMPLERA with food is important to help get the right amount of medicine in your body. A protein drink is not a substitute for food. If your healthcare provider decides to stop COMPLERA and you are switched to new medicines to treat HIV-1 that includes rilpivirine tablets, the rilpivirine tablets should be taken only with a meal.

Keep COMPLERA and all medicines out of reach of children.

This Brief Summary summarizes the most important information about COMPLERA. If you would like more information, talk with your healthcare provider. You can also ask your healthcare provider or pharmacist for information about COMPLERA that is written for health professionals, or call 1-800-445-3235 or go to www.COMPLERA.com.

Issued: June 2014

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THE COST OF LONG-TERM SURVIVAL

NEW FEARS EVOLVING WITH AGE

BY ENID VÁZQUEZ

"We long-term survivors get lost in the present atmosphere that says HIV is no longer a big deal. It is a big deal for us as we deal with the effects of long-term infection and the accumulated ravages of taking the meds. I feel alone and forgotten; and, I envy those who died back in the '80s and early '90s."

"Recently I had to add testosterone to my daily medication regimen and as soon as I get myself to the doctor for an A1C screening I know I'm going to be put on oral diabetes medication. I mean, when is enough enough? What is the reason for scraping to stay alive and healthy when there's nothing to look forward to but more chaos, uncertainty, and pain?"

"I recently read the question by someone [wondering] whether he 'deserved to live.' My question is, 'Do I want to live?'"

These are some of the comments HIV treatment advocate Nelson Vergel has received in his work with Ask the Experts at TheBody.com, a website devoted to people living with the virus. Earlier this year he sent out a message to the PozHealth listserv and to POSITIVELY AWARE, linking to these letters from readers who had virtually given up or who feared for their future.

Wrote Vergel, "I am getting so many emails like these. We really need to have a discussion about how prevalent depression while aging with HIV is, and how we should advocate for special services for the 'AIDS veterans.'"

The former chemical engineer and co-author of *Built to Survive* travels extensively

PHOTO: THINKSTOCK.COM

'MAYBE YOU HAVE PTSD

[POST-TRAUMATIC STRESS DISORDER],' A FRIEND TOLD HIM ONE DAY. IT SUDDENLY ALL BEGAN TO MAKE SENSE.

around the country giving talks on HIV nutrition, exercise, and treatment, so he constantly hears the concerns of people living with the virus. He wrote a blog entry entitled "The Long-Term Survivor Dilemma" three years ago, but said he's hearing more and more about the problems he discussed then, including a sense of shame about admitting fears.

"People wonder, 'Why have I tried this hard if my future doesn't look that great?' The thing is, those people can't say that to anyone because people say you should be happy you're alive, but sometimes we don't feel very happy to be alive," Vergel said. "We don't feel safe enough to admit any of this. Gay, straight, male, female—we had this intense fear of death. You're almost afraid to release it. And we are still waiting to be happy."

Vergel said he experiences mood swings, crying jags, numb emotions, and constant unexplained aches and pains.

"Maybe you have PTSD [post-traumatic stress disorder]," a friend told him one day. It suddenly all began to make sense.

"We don't have a place to go for vets with HIV. That's what we are—veterans of a war, but we don't have that recognition or support," said Vergel. "I had to bury all these friends and my boyfriend. I completely shut down that part of myself so I don't suffer. I don't cry and I don't grieve." He didn't even feel anything when his father died, making Vergel wonder what was wrong with him.

"We have concentrated on viral load and T-cells for 30 years, and we have neglected this side of us," Vergel said.

Although married to a psychiatrist, his long-term partner of 20 years, Vergel finds that only others who have lived his experience can understand it. "We're a minority within a minority. Only another person who's gone through it really gets it. People tell us, 'you need new friends' or, 'get out of the house more.'" Many, he points out, also continue to live with lingering body and facial changes from lipodystrophy as well, creating yet another stressor.

Having talked with people all over the country who are living with HIV and getting constant messages from many others, Vergel has seen that having survived trauma and perhaps not having dealt with it, long-term survivors now face renewed fears about illness, with all the added concerns of the later stages of life. As the epidemic shifted to one with viable medications, those who have survived the earliest days live not only with leftover health issues, but with the financial constraints that go hand-in-hand with medical care. Now there are health problems on the horizon with no foreseeable extra resources for those with limited incomes. Vergel's cancer diagnosis and chemotherapy last year brought out all these fears and insecurities.

In that blog entry, he wrote, "Many people with HIV on permanent disability struggle by on less than $1,000 a month to pay all their bills. Others who get payments from private disability policies from their last job will lose them when they reach age 65. But who thought we were going to live to be 65 anyway?!"

Vergel has eight friends who are set to lose their former job's disability income, and it terrifies them. The City of San Francisco is looking at its aging HIV-positive population and what will happen as those who have private disability plans reach retirement age and lose that income. The activist group Let's Kick ASS, or AIDS Survivor Syndrome (see page 16), is reaching out to people who are in this position. (Contact LKA co-founder Tez Anderson at Tez@LetsKickASS.org.)

"They feel trapped financially," Vergel says of long-term survivors. "They can't regain their financial health. There's lots of fear and depression, a lot of anxiety."

Vergel also wonders what will happen to nursing homes and other care facilities for those with the added layer of HIV. There might be a lack of LGBT-friendly places. "Where are we going to fit?" he asked. Then also, there are no non-profit organizations working on any of these issues, he said. "We're lacking creative solutions."

Meanwhile, bad news about aging and HIV continues to come out from medical journals and conferences. "We don't want to hear that," said Vergel. "We want solutions."

"We used to have retreats," he recalls. "We don't have the social networks we used to have. All we have now is the Internet."

One of the difficulties of long-term survivors is not wanting to appear weak or whiney. Said Vergel, "We try to live in the present and be happy, but there's also this ticking time bomb." PA

AUTHOR'S NOTE: Also read, "What we owe longtime survivors" by Victoria Noe at windycitymediagroup.com/lgbt/VIEWS-What-we-owe-longtime-survivors/49154.html.

NELSON VERGEL is starting a new website, HIVSurvivors.org.

THOUGHTS ON PrEP—FROM THE

BY TIMOTHY RAY BROWN

When I first heard about the introduction of the use of Truvada for PrEP (pre-exposure prophylaxis) in 2012, I did not give it much thought. I had been cured of HIV in 2007, and had been told by my doctors that I am immune to the virus. Therefore, I did not think that PrEP was something I needed for myself. Since the whole reason for all of my work is to help the HIV-positive community and their loved ones by giving hope that HIV can be cured, I eventually decided that PrEP is an important tool in preventing new infections and this is an extremely large part of my mission. This article will explain why my mindset toward PrEP for sexually active individuals and injection drug users has been transformed dramatically.

When asked by a leading HIV scientist at a conference in Marseille, France, in July 2012 what my thoughts on PrEP were, I said that since so many HIV-infected people were unable to access HAART, we needed to take care of them first rather than using precious resources to prevent further transmissions. Despite the fact that preventing HIV through "safer sex" did not work out so well for me, I thought that we already have prevention methods for HIV, and that those having receptive sex could just insist that their partners use condoms to prevent HIV.

However, I have since changed my mind.

In November 2013, my partner, Tim Hoeffgen, and I attended a PrEP debate in West Hollywood between a good friend of ours, Aaron Matthew Laxton, and the CEO of the AIDS Healthcare Foundation, Michael Weinstein. Weinstein had made public inflammatory remarks against people who choose to use PrEP to prevent HIV. Aaron supported the use of PrEP. I found that in contrast to his media opinion, Weinstein strangely admitted that PrEP does work if taken daily as prescribed. He also seemed convinced by the opposing argument that people on PrEP may have less of a tendency to spread other STDs because of the recommended quarterly medical checkups with HIV and STD tests. To me, his views seemed less hardline in that setting than his publicly broadcasted views. My mindset was beginning already to evolve at that point. Shortly thereafter, in order to learn more about the subject, I joined Damon L. Jacob's Facebook group *PrEP Facts: Rethinking HIV Prevention and Sex,* which offers in-depth discussions on PrEP.

Although I have been cured of HIV, I sincerely wish that PrEP had been available during my early years of sexual activity. I was diagnosed in 1995; I wish that I had never had to deal with the fear of thinking I only had about two years to live, or with the fear of judgment and stigma from friends, family, and the general public. I also had to take many pills daily for 11 years while being HIV-positive. For most people it means a lifetime of taking daily multiple medications, unless they are able to "join" my cure club. With PrEP back then, I never would have had to go through any of this. I wish this for all people who are currently at risk for HIV.

My partner and I in October attended the U.S. Conference on AIDS in San Diego. One of the sessions we attended was the *PrEPare for Life* workshop. Its speakers included several of NMAC's (National

FIRST PERSON CURED OF HIV

PHOTO: RAYMOND BORDEAUX PHOTOGRAPHY

Minority AIDS Council's) Youth Scholars, all of whom were young, gay men of color. Their knowledge and ability to speak about their reasons for choosing to use PrEP impressed me greatly.

A good example is Devin Barrington-Ward, who was already an advocate focusing mostly on black men and methods of HIV prevention. He was looking at ways to protect his clients from HIV infection. This led him as a black HIV-negative gay man to take his own advice and begin using PrEP himself at the beginning of 2014. When discussing changes in relationships, once he realized that he could date and have sex with positive people without worrying about HIV, dating had become much easier. He felt he had more freedom since he could share in the responsibility to remain HIV-negative himself. He had a few mild side effects at first, which went away. He has experienced virtually no stigma and says that it has even opened conversations with people who did not know about PrEP. For those on the fence on the subject, he said that people should ignore all of the arguments on both sides and seek more of the facts available on websites such as PrEPwatch.org or the National Minority AIDS Council's PrEPare for Life education and awareness program.

All of these influences have led to a change in my thinking about the use of PrEP to stem the rise in new HIV infections. If taken as prescribed, which means one pill daily, PrEP has been shown to be highly effective in reducing the risk of HIV transmission. The World Health Organization, Human Rights Campaign, and many leading HIV/AIDS organizations strongly endorse PrEP, and the Centers for Disease Control (CDC) has issued guidelines on its use. This ushers in a new wave of HIV prevention. I feel that if we are able to reduce the number of new infections, we could get closer to the objective of ending AIDS. The people who are not infected obviously cannot infect others.

While my ultimate goal is to see the end of AIDS, and a cure for HIV is extremely important, we also need to curb the rate of new infections. I believe that the use of PrEP is one of several methods now available to do that. Therefore, I have gone from feeling ambivalent about PrEP, to becoming a strong advocate for its use. PA

EDITOR'S NOTE: Read "He's Not Just 'the Berlin Patient': Timothy Ray Brown wants to help find a cure for everyone living with HIV" at positivelyaware.com.

CDC starts PrEP program for clinicians

The CDC has launched PrEPline, a free national service for clinicians **seeking advice and consultation about prescribing HIV PrEP**, the agency announced late last year. "When taken consistently, PrEP provides a safe, effective approach to reduce the risk of new HIV infection. However, many clinicians are unfamiliar with its use. PrEPline can serve as a valuable resource for physicians, nurse practitioners, and physician assistants who provide primary care for uninfected patients facing high risk of acquiring HIV." The PrEPline number is (855) HIV-PrEP (448-7737). For more information on services offered through the PrEPline, visit the National Clinicians Consultation Center at nccc.ucsf.edu. —ENID VÁZQUEZ

HIV/HCV CO-INFECTION NEWS FRO

BY ANDREW REYNOLDS

Approximately 10,000 doctors, researchers, and advocates from around the world gathered in Boston in November for the 65th Meeting of the American Association for the Study of Liver Diseases (AASLD), also known as "The Liver Meeting." Over 400 abstracts at the conference focused on hepatitis C (HCV), covering a wide array of issues and topics. This brief review will look at a select number of presentations on currently available HCV direct acting antiviral agents (DAAs) devoted to HIV/HCV co-infection.

Co-infection with HIV and HCV presents a number of challenges for the treatment of HCV, including but not limited to the faster progression of liver disease, poorer response rates to treatment, and drug-drug interactions with HIV medications. With few FDA-approved options for the treatment of HCV in people living with HIV, new options are needed. To that end, there have been several clinical trials of current and investigational HCV DAAs for this population, and a brief review of the results of this research follows.

WHAT'S APPROVED NOW: SOFOSBUVIR

Of currently available FDA approved treatments, an interferon-free option is available: sofosbuvir (SOF; brand name Sovaldi) and ribavirin (RBV). Jurgen Rockstroh presented results from the Photon-1 and -2 trials which looked at the treatment of HCV genotypes 1 to 4 in HIV/HCV co-infected persons. There were 497 people in these trials; some were treated for 12 weeks, and others were treated for 24. Within this group, 96% were taking HIV medicines with an average CD4 count of 605. **The SVR (sustained virologic response, or cure) results can be found in the chart on the following page.**

These cure rates are very similar to the results in people living with HCV mono-infection, and of added significance, none of the HIV-positive patients experienced a loss in CD4 T-cells (which does occur in interferon-based therapies) nor did there appear to be any drug interactions that led to an HIV viral load breakthrough. The regimen was also very well tolerated, with fatigue, insomnia, nausea, and headaches the commonly reported side effects, and only 15 participants discontinuing treatment due to adverse events.

These results show that this is an excellent option for treating HCV in people who are HIV/HCV co-infected, particularly for people with GT (genotype) 2 or 3, or those who cannot wait any longer for any of the newer DAAs to come on the scene.

NEW OPTIONS ON THE HORIZON

In a poster presentation, David Wyles and colleagues reported a 93.5% (29/31) SVR12 (at week 12) in HIV/HCV co-infected patients with HCV GT 1 who were treated with 12 weeks of the AbbVie regimen of ABT-450/r/ombitasvir and dasabuvir plus ribavirin, also known as the "3D" regimen. An additional arm comprised patients who were treated for 24 weeks and achieved an SVR12 of 90.6% (29/32). All patients taking HIV medications had an average CD4 count of around 625–633. Some of the participants had cirrhosis and the study included those who were both HCV treatment naïve and experienced. The most common side effects reported were fatigue, insomnia, nausea, and headaches, but the regimen was extremely well tolerated with no one discontinuing treatment due to side effects. Although this drug regimen is not yet approved, it was anticipated to go before the FDA for approval at the end of 2014, after this issue went to press. The results of this study offer hope for an effective new therapy for treating HIV/HCV co-infected people, but the numbers of participants are relatively small and further study (both currently ongoing or planned) is needed.

Mark Sulkowski and colleagues presented the final results of the C-Worthy Study, a randomized, open-label Phase 2 clinical trial looking at the effectiveness of the Merck drugs grazoprevir and elbasvir with or without RBV (ribavirin) for the treatment of HCV GT 1 in HIV/HCV co-infected persons. The study participants were split up into two groups with 97% (28/29) in the RBV-based regimen achieving an SVR12 and 87% (26/30) of those without RBV achieving an SVR12. This regimen was very well tolerated with headaches and fatigue reported, and no one stopped treatment due to adverse events. These promising results support the move of these drugs into Phase 3 clinical

M THE 2014 LIVER MEETING

Sovaldi + ribavirin

SVR (sustained virologic response, or cure) results in HIV/HCV (Photon-1 and -2)

GENOTYPE	12 weeks	24 weeks
GT 1	NA	81% (182/226; treatment naive)
GT 2	89% (40/45; treatment naive)	90% (27/30; treatment experienced)
GT 3	67% (28/42; treatment naïve)	91% (52/57; treatment naïve) 88% (58/66; treatment experienced)
GT 4	NA	84% (26/31; treatment naive)

trials, which are ongoing and will likely be reported this year.

HARVONI FOR HIV/HCV CO-INFECTION

On October 10, 2014 the FDA approved the Gilead drug Harvoni. Harvoni is a fixed-dose combination of ledipasvir/sofosbuvir (90/400 mg) for the treatment of HCV genotype 1. This FDA approval is for the treatment of mono-infected HCV, but not for HIV/HCV co-infection, although it can be prescribed off-label for this group.

In a small, open-label study of 50 patients, researchers at the National Institute of Allergy and Infectious Diseases (NIAID) studied the safety, tolerability, and efficacy of Harvoni in people living with HIV/HCV. All of the study patients were treatment-naïve, and none had cirrhosis. There were 13 people who were not on antiretrovirals, and 37 who were taking them. The group was 74% male, and the average age of the group was 59 years old. African Americans comprised 84% of study participants and 78% had the harder to treat genotype 1a.

The results of the study were remarkable: 98% (49/50) achieved an SVR12. The side effects were relatively mild, with nasal congestion, nasopharyngitis, and teeth issues most commonly reported (but even here, the numbers were very few). The more commonly known side effects such as fatigue, nausea, and headaches were also reported, but at very low numbers. No one had any serious adverse events while on treatment, and no one stopped treatment due to side effects. Of equal importance—no one experienced any changes in their HIV viral loads nor did they have lower CD4 counts while on HCV treatment.

The one participant with treatment failure did not have an undetectable hep C viral load at the end of treatment, but experienced an early viral relapse two weeks post-treatment. There did not appear to be any glaring reason for the relapse, but as this can happen with mono-infected patients too, it is a subject that researchers will continue to monitor and study so we can learn how to best re-treat people for whom the medications do not work. Additionally, one participant was recently found to have a detectable HCV viral load at 36 weeks, but it is too soon to tell if this is a re-infection or not.

In the end, this small study shows that the LDV/SOF combination is as safe and effective in co-infected patients as it is for mono-infected ones. This is great news for people living with HIV/HCV who are looking for an interferon- and ribavirin-free HCV therapy. As it is not yet FDA approved for the treatment of HCV in co-infected persons, any doctor who prescribed this would be doing so "off label" (that is, not FDA approved, but has scientific backing for its use, as limited as the evidence may be), so it might be hard to access it at this time. This drug combination is currently under study in co-infected individuals in a Phase 3, open-label trial.

CONCLUSIONS

Both currently and soon to be available HCV DAAs offer much hope for people living with HIV and HCV. Cure rates look to be very similar to those of mono-infected persons, and the regimens appear to be safe to take with HIV medications and do not impact CD4 counts. This optimism needs to be tempered a bit by the relatively small numbers of patients in these studies, but ongoing clinical trials will provide us with more information in the year ahead. PA

ANDREW REYNOLDS is the Hepatitis C Education Manager at Project Inform.

RESOURCES

ALTHOUGH THIS ARTICLE MENTIONS A SELECT NUMBER OF ABSTRACTS THAT WERE FOCUSED ON HIV/HCV CO-INFECTION, IN ALL, OVER 400 ABSTRACTS WERE PRESENTED AT THE 2014 LIVER MEETING. YOU CAN LEARN MORE ABOUT STUDY RESULTS AND NEWS FROM THE CONFERENCE FROM THESE SOURCES:

Project Inform
projectinform.org

HIVandHepatitis.org
hivandhepatitis.org

HCV Advocate
hcvadvocate.org

NATAP
natap.org

YOU CAN ALSO CALL THE AUTHOR (AS WELL AS HIS COLLEAGUES) ON THE SUPPORT PARTNERSHIP'S NATIONAL HEPATITIS C PHONELINE, (877) HELP-4-HEP, (877) 435-7443, ABOUT RESULTS FROM THIS CONFERENCE, AS WELL AS HCV PREVENTION, CARE, AND TREATMENT.

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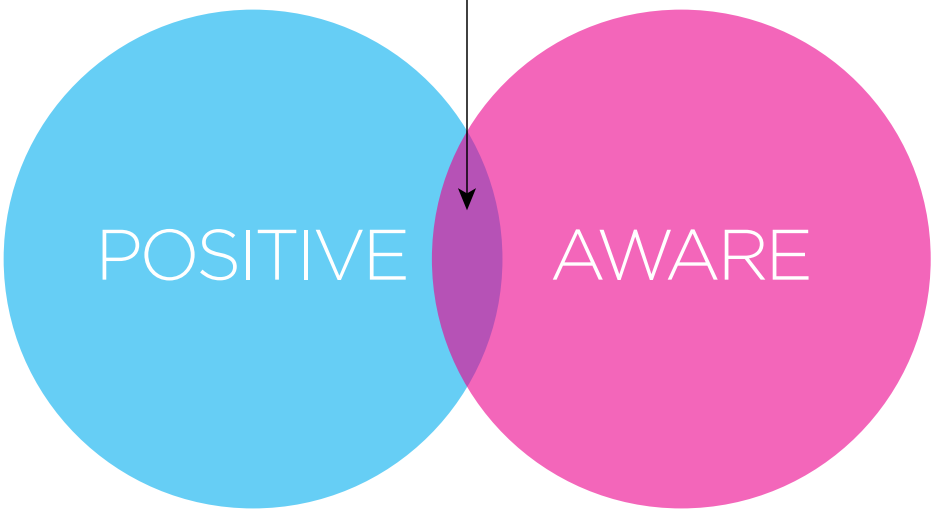

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