

# House of Numbers

"Leung manages to present a barrage of intriguing theories debunking our generally accepted beliefs... There's no denying, however, the value of exploring such game-changing topics as how HIV-infection numbers are cooked for monetary and political gain; how the effects of global poverty may have led to so many AIDS-related deaths; how such widely used AIDS drugs as AZT have, themselves, often proved fatal; and whether HIV really exists." Gary Goldstein, Los Angeles Times

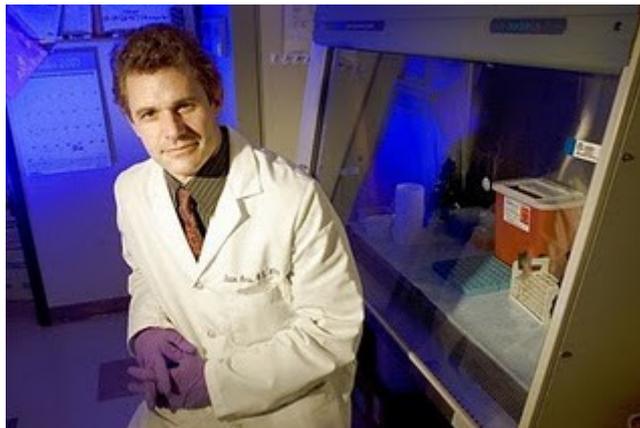
## Wednesday, June 16, 2010

### [Study reveals promise for HIV test](#)

**Early detection hope of S.D. researchers**

By [Keith Darcé](#), UNION-TRIBUNE STAFF WRITER

Tuesday, June 15, 2010 at 12:05 a.m.



The evolution of AIDS from a deadly disease shrouded in fear to a largely manageable condition took another step forward Monday, when San Diego researchers unveiled results of a study looking at an early-detection method for the virus that causes the illness.

The report's authors said a rarely used blood test can spot HIV weeks before the body recognizes the infection. They recommended that it be offered along with the more common screening method to people at high risk of contracting the virus, including gay men, intravenous drug users and people with multiple sex partners.

Among the 3,151 participants in a two-year study, the blood test identified HIV in 15 individuals who had falsely tested negative with the traditional saliva swab procedure.

False negative results occur in as much as 1 percent of those who take the swab test, which pinpoints antibodies produced by the immune system in response to infection. It can take as long as three months for the body to begin producing enough antibodies to trigger a positive reading.

During that lag time, people can unknowingly spread HIV through unsafe sex and miss early treatments that could improve their health in the long run, said Dr. Sheldon Morris, an AIDS researcher at the [University of California](#) San Diego's Antiviral Research Center in Hillcrest.

Morris was lead author of the HIV-testing report, which appeared Monday in the journal *Annals of Internal Medicine*. His colleagues included other researchers from UCSD and San Diego County's HIV, STD and Hepatitis Branch.

"If people got an antibody test alone and were told they weren't infected when they were, they could be a strong infection risk until they get tested again, which according to guidelines could be six to 12 months later," Morris said.

The latest findings reinforce similar conclusions from a 2005 study led by scientists at the [University of North Carolina](#). Those researchers administered the early-detection blood test to a much larger sampling of people.

Participants in the San Diego study whose blood tested negative could get their results in person, through an automated telephone system or by logging on to a secured website. About 65 percent of those who sought their results used the automated options.

Morris said the pattern demonstrates a shift in attitudes about AIDS. The illness once was viewed as a death sentence that needed in-person counseling to deal with issues such as shame and secrecy. But advances in detection and treatment have turned it into a chronic, controllable condition for most patients — not unlike [diabetes](#).

"HIV is not as mysterious as it once was," Morris said.

The early-detection blood test, which homes in on nucleic acid RNA molecules produced by the virus, has been used to screen most of the nation's blood donation supply since 2002, according to its maker, [Gen-Probe](#) of San Diego.

The [FDA](#) approved the test for use as an HIV diagnostic tool in late 2006, but its cost — as high as \$100 — and more complicated administration have helped discourage widespread use, said Rowena Johnston, vice president and research director of the New York-based international [HIV/AIDS](#) research foundation known as AMFAR.

Samples for the blood test are obtained through finger pricks and must be sent to a laboratory, which can take up to two weeks to return results.

"The reason the antibody test is (widely) used is because of low cost and convenience," Johnston said. The saliva swab method can produce a reading within a few minutes.

But identifying people with HIV within a few days or weeks of infection has become a public health imperative, in part because the virus level tends to be highest during the early infection stage — making transmission to others more likely, she said.

"This really is a key to preventing HIV transmission," Johnston said.

Because of the blood test's cost, health experts said, it probably isn't practical to offer the higher-level screening to the general population. It makes more sense to focus on high-risk HIV groups because they record larger numbers of false-negative antibody test results.

In the San Diego study, participants were recruited from several HIV testing sites in the region, including those run by UCSD, the county and the Lesbian, Gay, Bisexual, Transgender Community Center.

Each participant was given the saliva swab test, and then blood samples were taken from those who tested negative. The samples were sent to labs in San Diego and Emeryville in the Bay Area, where they were analyzed for HIV nucleic acid. Patients who tested positive for HIV after the blood analysis received the results from clinic staffers within a week.

Morris said the blood test is sensitive enough to detect the virus components within 10 days of infection.

“I think the time is coming where we will have to adopt a strategy for earlier (HIV) detection,” he said. “If you have a testing site with a high-risk prevalence, then you probably should be running this test on all of their samples” that tested negative for virus antibodies.

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See [House of Numbers](#) to learn more about HIV and AIDS.

[Watch HIV scientists Dr. Niel Constantine and Robin Weiss talk about the accuracy of HIV Testing.](#)

[Watch Prof. Luc Montagnier, discoverer of HIV talk about clearing the virus naturally.](#)

House of Numbers Anatomy of an Epidemic at [1:13 AM](#) 0 comments   [Links to this post](#)

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## Sunday, June 13, 2010

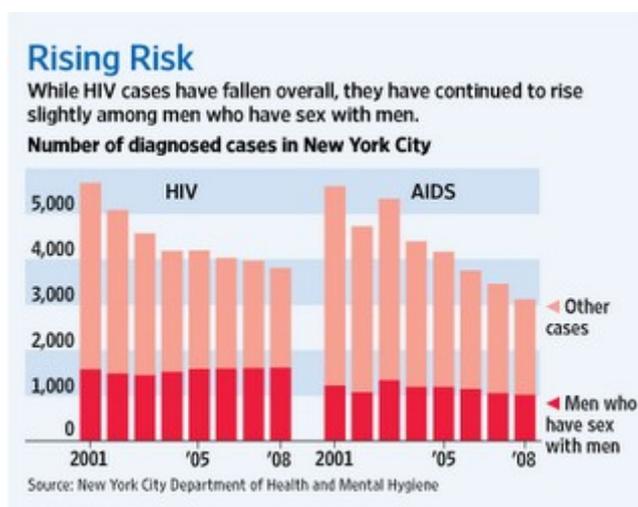
### [AIDS Budget Faces Reduction](#)

#### Prevention Efforts by Community Groups Face Cuts

By [SUZANNE SATALINE](#) And [SHELLY BANJO](#)

New York City's efforts to stem the spread of HIV/AIDS could shrink under the proposed cuts in the city budget, as the total number of new cases has been declining. But health officials are worried about a rise in HIV diagnoses among men who have sex with men.

Mayor Michael Bloomberg's budget proposal for the new fiscal year calls for slicing \$428,000 from the current year's \$14.6 million spent on HIV prevention efforts done under contracts with community-based organizations, officials with the city Department of Health and Mental Hygiene said. The cuts would amount to about a 3% reduction in dollars spent on AIDS prevention contracts for the fiscal year starting July 1.



Overall, new diagnoses of HIV and AIDS cases in the city fell between 2004 and 2008, the most recent figures available. The city logged 3,809 HIV diagnoses in 2008, compared with 4,186 in 2004, a 9% drop. The total number of people living with HIV/AIDS has risen nearly 10% in four years, to nearly 106,000 people in 2008.

While diagnoses overall have dropped, they are climbing among men who have sex with men. The city noted 1,614 cases of HIV among this group in 2008, up less than 1% from the previous year, but nearly 6% higher than in 2004, when that number was 1,527.

The city noted that 330 men in this group had concurrent AIDS diagnoses—a diagnosis within a month of a positive HIV test. That's an increase of 30 cases, or 1% more, than in 2007 and 18% more than 2004. Proportionately, more black and Hispanic men are affected in this category, health officials said.

Health officials and health-care workers say the rise has been caused by greater risk-taking among young men.

Men under the age of 30 "have no recollection" of the 1980s, when contracting AIDS was a fast death sentence, said Monica Sweeney, the city's assistant health commissioner. "The fear factor is completely missing." Young men also have the false belief, she said, that if they contract AIDS, "all you have to do is take one pill a day."

Harlem United, a social-services organization that relies on city funding to perform prevention work, said the \$300,000 city grant it received has been used to train 120 volunteers to talk with men in online chat rooms, urging participants to get tested and to use condoms.

"You infiltrate the social network," said Sara Gillen, vice president for the group's prevention division. Over time, "we're training them to prepare them for a lifetime of prevention strategies," she said.

Nationwide, AIDS organizations have reported a sharp decrease in federal aid and donations. Part of the reason is donor fatigue: In New York, AIDS has moved from being viewed as an epidemic to an endemic problem, according to Len McNally, director of the NYC AIDS fund at the New York Community Trust.

The trust, the largest private funder of New York City nonprofits, saw private funding it receives for AIDS-related causes drop to \$1.7 million in 2008 from \$2.3 million in 2003.

Regarding the proposed budget cuts, a spokesman for the mayor's office said it doesn't tell each department what specifically to cut, and referred comments to the health department. A health department spokeswoman said: "We have to make cuts across the board. We're preserving the highest quality prevention programs."

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Watch [House of Numbers](#) to learn more about HIV and AIDS.

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Labels: [African AIDS](#), [AIDS](#), [AIDS Drugs](#), [America](#), [Budget](#), [Health](#), [HIV](#), [HIV isolation](#), [HIV Tests](#), [New York](#), [NYC](#)

**Wednesday, June 9, 2010**

**Fungus-tainted corn a factor in Africa HIV spread?**



(Reuters Health) - A new study raises the question of whether corn contaminated with a fungus-derived toxin is helping to facilitate the transmission of HIV in sub-Saharan Africa.

**Health**

The toxins, called fumonisins, are produced by a particular type of fungus that can grow in corn after the plant is damaged by pests such as the cornstalk borer.

Fumonisin may be harmful to human health, with some studies linking consumption of the toxins to an increased rate of cancer of the esophagus, the tube that connects the throat to the stomach.

In the new study, published in the American Journal of Clinical Nutrition, researchers looked at whether there may be a relationship between HIV transmission in sub-Saharan Africa and general consumption of foods prone to contamination with fumonisins or other fungus-produced toxins (known as mycotoxins).

Using data from the World Health Organization and the Food and Agriculture Organization, the researchers found that as sub-Saharan countries' per-person corn consumption rose, so did HIV transmission rates.

In countries with a relatively higher percentage of Muslims -- a factor linked to lower HIV rates -- those with high per-capita corn consumption had an estimated HIV infection rate of 291 per 100,000 people in one year. In contrast, the rate in those with low corn consumption was 74 per 100,000 people.

Meanwhile, in countries with both fewer Muslims than average and higher-than-average corn consumption, there were 435 HIV cases per 100,000 people.

The researchers also found that higher per-capita corn consumption correlated with a higher rate of esophageal cancer. Since fumonisin toxins have been linked to that cancer, the finding serves as an indicator that populations with high corn consumption were exposed to higher levels of the toxin.

What all of this means is not yet clear. This appears to be the first study to find an association between corn consumption and HIV transmission rates in sub-Saharan Africa, lead researcher Dr. Jonathan H. Williams, of the University of Georgia in Griffin, told Reuters Health in an email.

The findings, he and his colleagues say, must be considered preliminary and need to be backed up by further research.

It is biologically plausible that high fumonisin intake could make a person more vulnerable to HIV infection. According to Williams, research suggests that the toxin makes certain tissues more

vulnerable to infections by viruses.

A number of factors have been identified as key in sub-Saharan Africa's HIV transmission rates; male circumcision, for example, has been shown to lower heterosexual transmission, while having multiple concurrent sex partners or other sexually transmitted infections increases the risk.

The current findings raise the possibility that food safety -- in particular, the issue of fumonisin-contaminated corn -- is an additional factor.

Based on their statistical model, Williams and his colleagues estimate that if the "maize (corn) factor" were eliminated in sub-Saharan Africa, HIV transmissions could be cut by as much as 58 percent.

Contamination might be prevented, for instance, by planting corn varieties genetically modified to be resistant to pests. It may also be possible to remove contaminants, Williams said, through certain milling technologies or by soaking the grain in water; fumonisin is water-soluble, so "steeping" the grain or meal, then discarding the liquid may remove the toxin.

In a region where an estimated 1.7 million people become infected with HIV annually, that would mean more than 1 million infections averted each year, the researchers note.

All of that, however, remains speculation until further research is done confirming the link between contaminated corn and HIV.

SOURCE: [link.reuters.com/bad29k](http://link.reuters.com/bad29k) American Journal of Clinical Nutrition, online May 19, 2010.

Article Source: <http://www.reuters.com/article/idUSTRE65848I20100609>

[Watch House of Numbers to learn more about HIV and AIDS.](#)

[Click here to see Luc Montagnier's views on clearing HIV naturally.](#)

[House of Numbers](#) now available on [iTunes](#) and [Amazon.com](#)

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**Tuesday, June 8, 2010**

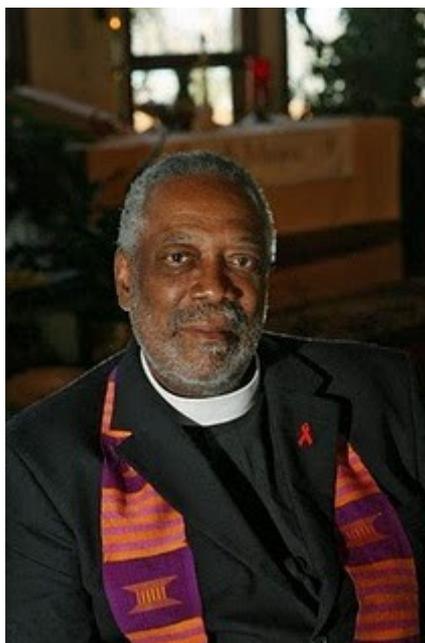
**[Meharry, ministers team up to fight HIV/AIDS in Nashville](#)**

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Federal grants to support programs

By Andy Humbles • THE TENNESSEAN • June 7, 2010

**HIV and AIDS isn't an easy subject for churches.**



“I think HIV and AIDS is a more difficult challenge because of the necessity of addressing human sexuality that, in many instances, there has been a reluctance for many churches to deal with,” said [Metropolitan Interdenominational](#) founder and Senior Servant, the Rev. Edwin Sanders. Two federal grants, one to Metropolitan Interdenominational Church and one to [Meharry Medical College](#), are designed to put churches and faith leaders in a position of leadership in the battle against HIV and AIDS.

Both are recipients of a [Capacity Building grant](#) from the Center for Disease Control and Prevention. Each grant will total nearly \$2 million over five years.

Metropolitan Interdenominational and Meharry will operate independent models, but each with a heavy emphasis to equip clergy with the skills and expertise to establish successful HIV and AIDS prevention programs.

The grants are designed to involve health providers and Historically Black Colleges and Universities as well.

“The church needs to be involved on several levels,” said the Rev. Sherman Tribble, pastor of New Visions Baptist in Donelson. “One is spreading the news that’s it’s an equal opportunity disease. Anyone who is human has the possibility of getting it.

But that there is also healing and hope. Who can say that better than the church?”

It’s the third time Metropolitan Interdenominational has gotten a CDC grant. The church has been active in HIV and AIDS prevention for about 25 years now. Its first CDC grant was for four years and the second was for five. It’s Meharry’s first CDC grant of this kind.

The goal is to ultimately decrease AIDS and HIV numbers among African-Americans, which statistically has higher rates of infection in this country.

Metropolitan Interdenominational and Meharry work independently, but there will be collaboration.

#### **‘Clergy Circles’**

A primary component of the Capacity Building grant has been to hold summits and forums all over the country on HIV and AIDS prevention strategies that will attract clergy to attend. The goal is to

establish “clergy circles,” who will participate in a five-part curriculum based program.

The summits can attract 100-150 clergy and from those events hopes are about 30 will continue in the clergy circles.

“At the end of the curriculum-based program we hope we have established a level of commitment that will be sustainable,” Sanders said.

The present grant will continue establishing clergy circles with more intent on drawing from a regional area.

At the end of the last grant cycle Metropolitan Baptist had worked in 23 states, with programs established in Birmingham, Chicago, Clarksville, Savannah, Ga., Memphis and more. The outreach is called MICTAN (Metropolitan Church Technical Assistance Network). Sanders and MICTAN staff have most recently worked on establishment of a regional project in Rochester N.Y.

Another component of the church’s Capacity Building grant goes toward a relationship with divinity schools to help train future clergy. Metropolitan Interdenominational has primarily worked with the Howard University School of Divinity in Washington D.C. and American Baptist College in Nashville.

The church, with a congregation of about 350 on Sunday, has been active in numerous causes, including AIDS and HIV work.

One is a primary care clinic for HIV positive persons, funded by the church and Health Resource Service Administration under the Health and Human Services Department. The Capacity Building money does not go to the primary care clinic.

### **Project SAVED**

Meharry’s model, named Project SAVED ((Strengthening Access Via Empowerment and Diligence), has a 22-member advisory committee of ministers, health care providers and historically Black College leaders to work in an 11-state Southern region.

These advisers will engage their communities in the 11-state region around the HIV and AIDS issue to develop new prevention programs, activities and testing opportunities.

Southern region states are Tennessee, Alabama, Arkansas, Kentucky, North Carolina, South Carolina, Georgia, Florida, Mississippi, Louisiana, Texas, Oklahoma and New Mexico.

Dr. Jacqueline Hampton, is the director of the Community Outreach Core at Meharry’s Center for AIDS Health Disparities Research. Hampton is the Project SAVED director and sought and attained the grant.

“We should see more communities addressing the issue,” Hampton said. “When you see more communities addressing HIV, hopefully you see decreased incidents.”

Hampton felt Meharry’s location, the work its Center for AIDS Health Disparities Research has done and connections made with them ideally situated it to launch Project SAVED.

“We would have been remiss if we didn’t apply for the grant,” Hampton said. “What were trying to do is to grow the sphere of influence. We’re trying to penetrate areas that haven’t been penetrated.”

Advisory committee members will engage other community stakeholders to train and enhance Core team members represent other areas of the region and travel to meet and conduct workshops. One adviser is Sheila Dennie, the program coordinator for the National Minority AIDS Education and Training Center at Meharry, which is a separate program from Project SAVED.

“The community engagement model adds validity to the voice of the community,” Sheila Dennie, an adviser.

Tribble is among local pastors on the advisory team Meharry has established.

“Sometimes those from the medical community don’t have access to people in the faith community and sometimes we don’t have access to the medical community,” Tribble said. “It’s rare for a medical school to get involved ... We may see it one way and other service providers see it another. But we’re all doing our part.”

Source: <http://www.tennessean.com/article/20100607/DAVIDSON/100607058/Meharry-ministers-team-up-to-fight-HIV/AIDS-in-Nashville->

Note: *House of Numbers* premiered at the Nashville Film Festival in 2009.

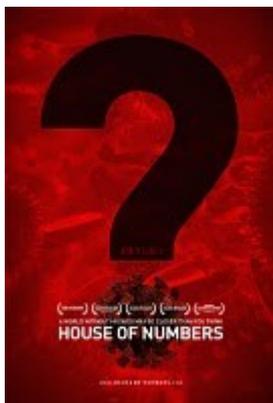
[Click here to read the Tennessean Review of HoN](#)

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## Monday, June 7, 2010

### [House of Numbers Adds Additional Content to its Deluxe Edition DVD](#)



*House of Numbers* has added full interviews to its [Deluxe Edition DVD](#) along with additional featurettes. A list of all the featurettes can be seen below and a list of full length interviews will be announced shortly.

#### [Deluxe DVD Special Features](#)

Behind-the-scenes: The Making of House of Numbers

Extended Interviews

32 Featurettes:

**HIV Testing**

- HIV Testing 101
- False Positives: Causes and Factors
- History and Evolution of HIV Testing
- Reading the Fine Print: HIV Test Inserts
- The Changing Criteria of Western Blot Testing
- Deciphering Test Results for False Positives
- Examining the "Gold Standard" for HIV Tests
- Testing of High Risk vs. Low Risk Populations
- HIV Testing Campaigns

## **AIDS**

- CDC: Initial AIDS Definition
- Creating an African AIDS Definition
- Bangui: AIDS By Numbers
- Bangui: Peripheral Psychological Damage
- Bangui Redux: National Variation in AIDS Definitions
- Through a Glass Darkly: African AIDS Statistics
- Clinical AIDS: A New Disease?
- A Growing Family: AIDS Marker Diseases and Indicators
- Bangui Westernized
- Politics and Public Health: A Study in Conflict
- CD4 T-Cell Count Marker: Medical Application
- 1997 - CDC Tables 11 and 12: Addition by Subtraction

## **Deconstructing a House of Numbers: Experts Examine Global HIV/AIDS Statistics**

- Dr. James Chin
- Rian Malan
- Dr. Charles Geshekter (Archival, 2001)

## **A Second Look**

- The "Probable Cause" of AIDS
- Dr. Don Francis on Dr. Robert Gallo
- Profile: Dr. Peter Duesberg

## **"Why I Began Questioning HIV" - Five Skeptics' Stories**

- Dr. Kary Mullis
- Rian Malan
- Neville Hodgkinson
- Dr. Rodney Richards
- Dr. Christian Fiala

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# Thursday, June 3, 2010

## **“HOUSE OF NUMBERS” NOW AVAILABLE ACROSS NORTH AMERICA ON VIDEO ON DEMAND**

**Los Angeles, CA – June 3, 2010** – It was announced today that the acclaimed HIV / AIDS documentary *House of Numbers* is now available in over 50 million North American homes with access to video on demand (VOD) offerings. Cable, satellite and telco operators playing the film in the United States include [Comcast](#), [Time Warner Cable](#), Cox, Charter, Verizon, Cablevision, [DIRECTV](#), DISH Network, RCN, Insight, Mediacom, and Suddenlink.

In Canada the film will be available to digital subscribers of Rogers, Videotron, Cogeco, Shaw and Telus. *House of Numbers* will also be available through Apple iTunes and on Amazon VOD.

One of the most buzzed about independent films of the year – the critically acclaimed and divisive HIV/AIDS documentary premiered theatrically in January 2010 but began making waves over a year earlier as it screened on the film festival circuit to tremendously curious audiences around the world, wanting to see a film that showcases how the HIV/AIDS story is being rewritten.

*House of Numbers* presents the uncensored POVs of virtually all the notable players in the HIV / AIDS world; in their own settings, in their own words. It rocks the foundation upon which all conventional wisdom regarding HIV/AIDS is based. The documentary raises new questions -- presenting global and conflicting viewpoints from an unprecedented array of over 30 of the most prominent and influential figures in the field, among them Nobel Laureates, the co-discoverers of HIV, Presidential advisors, the former Executive Director of UNAIDS, as well as survivors and activists. Surprising revelations and stunning contradictions are the result.

Commented director Brett Leung “We’re are very excited that audiences across North America will have easy access to experience ‘House of Numbers’. We believe Video on Demand is a great medium to further the ongoing discussion around the film.”

### **About the film:**

What is HIV? What is AIDS? What is being done to cure it? These questions sent Canadian filmmaker Brent Leung on a worldwide journey, from the highest echelons of the medical research establishment to the slums of South Africa, where death and disease are the order of the day. In this up-to-the-minute documentary, he observes that although AIDS has been front-page news for over 28 years, it is barely understood. Despite the great effort, time, and money spent, no cure is in sight.

The film unveils candid conversations on several key points: Why does the definition of AIDS change from country to country and over time? Why do esteemed scientists debate over the HIV virus? Are HIV tests reliable globally? Are the worldwide statistics correct? What are the dangers of the drug treatments?

Scientists and prominent figures featured in *House of Numbers* include: Professor Luc Montagnier MD, 2008 Nobel Prize winner for discovering the HIV virus, David Baltimore PhD, 1975 Nobel Prize winner; Kenneth Cole, Chairman of AMFAR; James Curran MD, who began his career with the CDC and held leadership positions for the CDC's HIV/AIDS research; Anthony S Fauci, Director of NIAID; Robert Gallo MD, PhD, co-discoverer of the HIV virus; Michael Gottlieb MD, credited as first doctor to diagnose AIDS; and Peter Piot MD, PhD, Director of Institute of Global Health and former Executive Director of UNAIDS.

First-time filmmaker, Brent Leung, grew up as part of the "AIDS generation" - he's never known a world without it. Yet with all of its notoriety, he realized the average person did not know that much about HIV and AIDS. What began as a 15-minute film project built around the simple question "What is HIV/AIDS?" revealed itself to be a much deeper journey. *House of Numbers* became a multi-faceted project that took him across five continents. Leung reveals a research establishment in disarray, and health policy gone tragically off course.

More information on the film can be found at [www.houseofnumbers.com](http://www.houseofnumbers.com).

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## **Friday, May 28, 2010**

### **FDA Panel Gives Thumbs Up for Egrifta**



From [Medscape Medical News](#)

**Fran Lowry**

May 28, 2010 — The US Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee has unanimously endorsed approval of tesamorelin acetate (*Egrifta*; Theratechnologies, Inc, Montreal) to induce and maintain a reduction of excess visceral abdominal fat in HIV-infected patients with lipodystrophy.

The committee based its approval on data presented by the sponsor that showed that 57% of patients taking tesamorelin experienced an 8% or greater reduction in abdominal fat compared with 29% of patients taking placebo.

The panel was also positively swayed by "compelling" testimony by 2 HIV-positive patients who told them how devastating it was to live with the unsightly accumulation of belly fat — an adverse effect of antiretroviral therapy — that immediately labeled them as "AIDS patients."

One by one, the 16 members of the panel gave their reasons for their yes votes. All said the sponsor clearly proved what they had set out to prove.

"I voted yes and it was an easy decision. The sponsor was asked to show a reduction of visceral adipose tissue and they did that," said Abraham Thomas, MD, MPH, division head of endocrinology, diabetes, bone and mineral disorders, Henry Ford Hospital, Detroit, Michigan. "They showed an improvement in patients' perception of their body image, that patients felt better

about their appearance. That's what they were asked to do and they did that very well in their series of clinical trials."

Clifford J. Rosen, MD, director of clinical and translational research and senior scientist at the Maine Medical Center Research Institute in Scarborough, also found that the decision to endorse tesamorelin was an easy one to make. He added that, in the short term at least, "there are few safety issues, so I didn't feel uncomfortable. This was not a hard choice."

### **Safety Concerns: IGF-1, Diabetes Risk**

But the panel did have safety concerns. Among them were concerns about increases in insulin-like growth factor 1 (IGF-1), which may promote tumor growth.

"I am very concerned about IGF-1," Dr. Rosen said. "There must be some way of labeling about frequent monitoring of IGF-1 levels. I think this is going to be a long-term issue. Currently, it's hypothetical, but it is a concern and both the patient and the prescribing physician should be aware of this."

Earlier in the day, some panel members had also expressed concerns about the increased risk for diabetes with tesamorelin. However, by the time it came to a vote, the panel felt that the benefits of the drug outweighed the risk.

"I harped a lot about diabetes and the risk factors, but I don't think we should be restricting people with HIV who have diabetes," Dr. Thomas said. "If someone has diabetes and is well controlled, that person should have an opportunity because they are suffering the same psychological issues of body image and being identified in the community as being on HIV treatment."

A similar opinion was expressed by David S. Schade, MD, professor of medicine and chief, Division of Endocrinology, University of New Mexico School of Medicine, Albuquerque.

"If this drug does not cause deterioration of glucose control, then it ought to be used in patients with diabetes. We should not exclude them," Dr. Schade said. "I would recommend that the FDA not include any language about excluding patients with diabetes. They can certainly say that there is no data supporting the use of this in diabetes, but I would hate to see all my diabetic patients potentially being excluded from this medication."

### **Prescribing Guidelines Requested**

Panel members also asked the FDA to come up with guidelines for clinicians in prescribing tesamorelin.

"As a clinician, I would like some specific criteria on when to stop Egrifta if the patient is not responding," said Princy N. Kumar, MD, professor of medicine and microbiology, Georgetown University School of Medicine, Washington, DC. "At what point, and with what measurements, do we say to a patient, 'you are not responding, we have given it to you for so many months and you are not going to respond any further'? I would like very concrete information on when to stop."

George A. Bishopric, MD, from Fort Lauderdale, Florida, who was the patient representative on the panel, commented that the degree of suffering that HIV patients with lipodystrophy experience, as well as the fact that there is no other agent for this indication, warranted approval. "We all want follow-up for cardiovascular issues, IGF-1, diabetes, and this will have to be done in postmarketing studies, but I am very happy that it passed."

"There is no question that lipodystrophy causes a fair amount of psychological distress, as well as difficulty in functioning. It has been associated with depression, and depression has been incontrovertibly associated with poor adherence and poor outcomes in disease progression," said Vicki Cargill, MD, director of minority research, Office of AIDS Research, National Institutes of Health, Bethesda, Maryland.

Dr. Cargill added that a registry or another form of postmarketing surveillance is needed, and other panel members agreed.

"The population in this study were mostly Caucasian and do not reflect the population that is heavily impacted by the epidemic, so it would be important to see data in such a population," she said.

The panel also debated whether reducing abdominal fat translated into a reduction in cardiovascular disease risk.

"The issue with regard to cardiovascular outcomes is certainly not shown at all by the sponsor, and we have no clue whether there is an adverse cardiovascular outcome or a benefit by reducing belly fat," said Mark E. Molitch, MD, professor of medicine at the Feinberg School of Medicine, Northwestern University, Chicago, Illinois. "This deserves study, whether through some registry or prospective placebo-controlled trials, which I prefer, but which might be difficult to do."

Source: <http://www.medscape.com/viewarticle/722647>

See [House of Numbers](#) to learn more about HIV Drugs

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