

Into Africa

Unprecedented Coalition of Activists and Human Rights Campaigners Targets GSK Actions

'Simply unacceptable'

The following letter, signed by hundreds of activists around the globe, was recently dispatched to the likes of Sir Richard Sykes, Jean-Pierre Garnier, David Stout, and John Kearney. They are, respectively, the non-executive chairman and chief executive officer (UK), the chief executive officer (UK), the chief operating officer (USA) and the chief executive officer (South Africa). As TAGline goes to press a lawsuit, filed by a coalition of 39 pharmaceutical companies against the South African government, had just begun at the Pretoria High Court, South Africa.

Dear Sirs:

We are writing as a coalition of AIDS treatment advocates, educators, and service providers to request that GlaxoSmithKline immediately withdraw from participation in threatened legal action regarding the importation of generic antiretroviral medications in Ghana and South Africa.

Specifically we refer to your threats of legal action against Cipla for selling *Duovir*, its generic form of *Combivir*, in Ghana (*Wall Street Journal*, 1 December

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"Companies that make generic copies are like pirates on the high seas. We don't believe in piracy. We tried to stamp it out in the seventeenth and eighteenth centuries."

Sir Richard Sykes
Chairman, Glaxo-SmithKline

Source: *Financial Times*, "Patents and patients," (February 17-18, 2001)

Columbia el Pendulum

Las Estrategías Clínicas Vienen y Se Van—Pero El Virus y Sus Pociónes Potentes Se Quedan

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'Imperativo para parar'

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Cada de vez en cuando, es útil a toma un cheque de la realidad. El día al mundo del día de la infección de HIV se refleja raramente en los vestíbulos del Congreso, los platos y los pozos de instituciones de investigación de biomedical o aún las páginas de Science o de Nature. Cuando el milenio naval de observatorio llega a su fin oficialmente, nosotros lo pensamos está interesado a la visita con los donadores del cuidado de la línea de la frente en uno del HIV comprensivo más grande del cuidado del país de facilidades. Los medicos y enfermeros del hospital San Vincente eran más que contento a se sienta para una charla. Y mientras algunos de sus observaciones se pudieran haber predicho, sorprenden todavía a ve cómo

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Prick Up Your Ears

Merck Makes Surprise Announcement of Human Vaccine Trial, Currently Under Way

'Partial protection' strategy

While a handful of companies are testing or have tested potential HIV vaccines in human volunteers, none of these trials has generated nearly the excitement of the latest announcement from officials at Merck. After shifting its vaccine screening program into overdrive some four years ago, Merck may now have something to show for its efforts. TAG's Mark Harrington was one of a limited number of activists invited to the company's closed-door presentation late last month, and there remain many unanswered questions. But in an era where news of potential therapeutic breakthroughs is harder and harder to come by, we thought it prudent and perhaps even inspiring to briefly summarize the few hard facts currently at hand.

Late last month Merck announced that it has begun human trials of a new experimental HIV vaccine which has generated quite a bit of excitement within the scientific community. The trial, which began just a few weeks ago, is first being conducted to assess safety in healthy, uninfected adult volunteers.

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although they are using a different vaccine construct (see the January 2001 *TAGline*). Similarly, collaborative research teams at Emory University/NIAID and Yale University/Aaron Diamond Research Center have also presented results with similar approaches. But the Merck product is the first of these to actually enter human clinical trials. The Yale/Aaron Diamond vaccine, however, may also soon move into human trials.

Part of the excitement over the Merck announcement stems from the company's long history of vaccine research and development. Merck is one of the world's largest and most experienced vaccine manufacturers (along with SmithKline and Pasteur Merieux). Even as Merck plays down expectations for its newest vaccine strategy, it is not ruling out the possibility that the vaccine might still prove to be protective in humans. Part of this speculation derives from the fact that the challenge dose in the laboratory animals was much greater and much more virulent than what a human to human inoculum would typically entail. But at the current time, this possibility remains speculation.

In fact, Merck appears to be quite concerned that even the snippets of information that have been allowed to leak out up to this point may result in undue expectations and inevitable disappointment. Even if the vaccine were to prove successful, Merck officials caution, it would still not be available for years. And it is still very possible that the vaccine could simply fail.

One additional possible benefit to this partial protection approach—whether with the Merck candidate or the Harvard, Emory or Yale construct—is the additional application to individuals already infected with HIV. Simply put, if any of these vaccines does

March 5th: Day of Global Direct Action for Drug Access

An international coalition of 65 activist groups and over 100 AIDS activists, educators, health care workers and service providers from six continents and many countries around the world today called on GlaxoSmithKline, one of the world's largest drug companies, to withdraw threatened lawsuits in Ghana, Uganda, and South Africa which are intended to block people with AIDS (PWAs) in those countries from having access to generic anti-AIDS medications.

The coalition, led by the Health GAP Coalition, Treatment Action Group (TAG), and Gay Men's Health Crisis (GMHC), took this action because in November 2000, Glaxo threatened to sue Cipla Ltd. of India, a generic pharmaceutical manufacturer, if Cipla continued to sell its generic *Duovir*, a combination of the AIDS drugs AZT and 3TC (marketed by Glaxo as *Combivir*).

In addition, Glaxo has joined forty other drug companies in suing the South African government for a 1997 law intended to broaden access to cheap generic drugs in South Africa.

The activists wrote, "We believe that threatening lawsuits to prevent people in poor countries—already staggering under the weight of the AIDS pandemic, excessive debt to western banks, poverty, and underdevelopment—from accessing life-saving antiretroviral medications is simply unacceptable from a moral and humanitarian point of view."

Instead, the activists suggested that Glaxo: Immediately reduce antiretroviral drug prices to levels affordable in poor countries;

Match the best generic offering price (Cipla's *Duovir* sold for \$1.72 retail in Ghana); Provide free antiretrovirals in drug donation programs; and/or Allow poor countries to permit generic manufacturers to make or import the drugs.

TAG Senior Policy Director Mark Harrington said, "We are announcing today a Global Day of Solidarity on March 5, the day when the Pharmaceutical Manufacturers Association of South Africa's lawsuit against legal generic drug access comes before the court in South Africa. On that day, some groups will take direct action against drug companies, pharmaceutical trade organizations, or the U.S. Trade Representative, which has just brought action against Brazil for manufacturing generic antiretrovirals. The program in Brazil is reaching over 85,000 people with AIDS and has saved thousands of lives. No other program - whether the UNAIDS Accelerating Access initiative or the much-touted, but so far insignificant, discounts announced by five big drug companies last May - are reaching significant numbers of people with HIV in the world's poorest countries."

eventually prove capable of augmenting the body's natural immune defense against the virus, it might be reasonably expected to be useful as treatment. And Merck seems amenable to just such a two-pronged development strategy. The company has said that it is quite willing to test whether the vaccine might be useful for the treatment of people already infected with HIV. In

fact, a recent company announcement reported that Merck will begin testing the vaccine in HIV-infected study volunteers within the next three months. For now, all we can do is watch and wait. Fingers crossed. †

fesor colegial y de otro modo se siente bien?

Siegel: No era multidermatomal, era?

Bailey: Nosotros no sabemos todavía.

Siegel: Porque cuando usted habla acerca de zoster que usted tiene que pensar en el pitfalls de STIs también. Tuve una experiencia muy interesante. Uno de mis pacientes que es bastante mayormente, él es un hombre en su temprano 70s ahora, presentado con un palsy de la Campana. Eso es cómo su infección de VIH se diagnosticó. Mostré Juan este caso. El hombre muy agradable, muy diligente acerca de tomar sus píldoras pero odió tomarlos. ¿Siguió agitando apenas, usted sabe, "por qué tengo que tomar yo tan muchas píldoras?" ¡Y él hacía magnífico! El tuvo, yo no sé, cuántos CD4s, pero él tuvieron la abundancia de la habitación para la maniobra. Y tan, acerca de hace dos meses yo paré sus antiretrovirales y, espalda que mira, él nunca había tenido una carga muy alta de viral cuando comenzamos a la medida él. Y lo y percibe dentro de un mes él tuvo su espalda de palsy de Campana. Y puse él apoya en HAART y en el aciclovir, y se va. Pero era tal una recapitulación llamativa de lo que había acontecido previamente. Y esto acontecerá como paramos. Y es presumiblemente la misma clase de la cosa como tener un síndrome agudo de retroviral, cuando usted para HAART.

TAGline: El viral carga alcanza el máximo jamás y regresa abajo por sí mismo?

Siegel: Sí... si usted mira en una base semanal, o una dos veces a la semana base. Hay un pico pequeño y entonces se baja un pequeño y alcanza una meseta.

TAGline: Porque he oído las anécdotas de los casos donde..

Siegel: Pero la pregunta es, "¿Significa algo?"

TAGline: Pero si qué ejemplares anormales usted fuera es el virus' ir a 150,000 o 200,000, pero entonces un mes posterior está de vuelta hacia abajo.

Siegel: Yo nunca lo he mirado eso temprano.

Olmscheid: Usted tiene que esperar hasta que usted esté en esa fase de meseta a determina lo que alguien carga crónica de viral es.

Siegel: Y no es necesariamente fijo. La mujer joven que yo me referí a era antes alguien yo paré. En acerca de un mes que ella tuvo acerca de 7,000 copias. En acerca de dos meses, ella tuvo acerca de 15,000 copias. En acerca de diez meses, ella tuvo 660,000 copias. Tan acaba de subir de mantener, pero lo hizo lentamente. No lo hizo todo eso bruscamente. Ella podría haber tenido un pico temprano, pero

ella era completamente asintomático y ella son finos. Sus células T son todavía excelentes. Yo me siento en ella pero muerdo mis clavos. Pero eso es la clase de la cosa que acontece. Hay una respuesta enormemente diversa cuando se para la terapia. †

TAGline is published monthly by the Treatment Action Group (TAG), a 501(c)(3) non-profit treatment advocacy organization in New York City.

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Treatment Action Group
350 Seventh Avenue, Suite 1603
New York, NY 10001
Tel. (212) 971-9022
Facs. (212) 971-9019
E-mail: tagnyc@msn.com
www.treatmentactiongroup.org

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