Adios Mexico, Gracias Tony y mas

August 8, 2008 By Paul Dalton

It is my last day in Mexico City and I am going to try and see and enjoy some of the city (outside of my little out of the way hotel and the lovely Banamex Center). Below is an article I wrote for Project Inform's web coverage of the conference. It is about Tony Fauci's plenary talk. It was one of the highlights of the meeting for me.

There will be more coverage from the conference showing up next week, when I am back in the office including

Does Abacavir cause heat attacks?
Does Abacavir work for people with high viral loads?
The Trio Study
and much much more.

Tony Fauci lends support to focus on cure
by Paul Dalton, August 7, 2008

In a fast moving and wide ranging talk at the International AIDS Conference in Mexico City, Dr. Anthony Fauci, the head of National Institute of Allergies and Infectious Diseases at the NIH, gave new hope and energy to the defining call of AIDS activism, ?Until There is a Cure.? While necessarily short of details, the vision that Dr. Fauci presented points the way forward for both the research community and the activist world.

In his talk, ?The Future of AIDS Research,? Dr. Fauci took a broad approach to priorities for research ? and by extension ? advocacy. He looked at 6 key areas, all in a brisk 20 minute presentation: pathogenesis, diagnostics, therapy, prevention, vaccines and, finally, the cure.

Pathogenesis
In the arena of pathogenesis (how HIV causes disease), Fauci pointed to the need for a deeper understanding how the virus interacts with an infected person?s immune system. He focused specifically on the events of early infection when HIV accomplishes a ?double whammy?: seeding compartments of the body to establish a reservoir while simultaneously dampening its own immune response by killing the CD4 cells which then produce substances to dampen the immune response.

He suggests that this earliest phase of HIV disease as both a time of vulnerability and opportunity.

If one was able to intervene during these early events, it might have profound effects on the course of HIV disease.

Fauci also pointed to the promise of cutting edge technologies to speed up the drug development process. As an example, he mentioned the paper published this February in the journal Science in which researchers detailed over 270 proteins involved in HIV replication. Only 36 were previously known to play a role in HIV replication. ?This opens up literally scores of potential new drug targets,? Fauci said.

The HIV drug development pipeline badly needs this kind of reinvigoration. The current crop of experimental agents holds very little promise for significant breakthroughs in HIV treatment. This is particularly disappointing when seen in the light of recent findings on two of the newest drugs: Isentress (raltegravir) which seems to lower HIV levels more quickly and possibly thoroughly than other drugs, and Selzentry (maraviroc) which appears to have anti-inflammatory properties.

Diagnostics and monitoring
Dr. Fauci then detailed the important work to be done in research on diagnostics and other kinds of monitoring: the need for effective, low cost diagnostic tools in the developing. One of the significant obstacles to the effective delivery of anti-HIV treatments in the developing world has been the high cost of crucial diagnostic and monitoring tests like CD4 counts and HIV viral loads. Adding to his call for greater work in these areas, Fauci also stressed the importance of reliable and widely available TB tests in the developing world.

Former Project Inform staff member, Ben Cheng, currently working with the DC-based Forum for Collaborative HIV Research, has done groundbreaking work bringing together scientists and other stakeholders in an effort to develop and test low cost diagnostics for use in developing countries. Without these tests, which are a central part of care in the US and other wealthy countries, the full benefit of HIV treatment can not be realized.

Treatment
Dr. Fauci contrasted the breathtaking progress made in HIV treatments against the fact that we continue to lose ground to HIV worldwide. He cited a report published in the July 2006 issue of Journal of Infectious Diseases that found that HIV treatments had saved 3 million years of life in the US alone. He also showed the real progress made in increasing the number of people in middle and low income countries on HIV treatments, growing from just a few hundred thousand in 2002 to over 3 million today.

This good news is blunted, however, by the fact that for every person put on HIV treatment, 2 to 3 become newly infected by HIV. Worldwide, fewer than 1 in 3 people who need these proven treatments have access to them.

This needs to be seen in light of declining interest by the pharmaceutical industry in HIV. As Project Inform recently wrote about, fewer companies are getting into the HIV game, and some long established players are decreasing their involvement or getting out all together.

While pharma as a whole is doing well, the future for its involvement in HIV is grim. Many of the earliest generation of HIV treatments will see their patents expire over the next few years. This will lead to declining HIV-related profits for these companies. Unfortunately, history has shown us it?s unlikely to result in lower drug prices for consumers.

New energy and new products can reinvigorate pharma?s response to HIV. As mentioned above some of the newer agents have shown hints of game-changing properties. The industry needs to build on these gains and develop the next generation of HIV treatments, ones that overcome some of the potency and tolerability limitations of the current treatments.

Prevention

One of the most widely covered stories here in Mexico City is the overall sense of frustration with prevention efforts. The CDC?s 40% upward revision in the number of new HIV infections each year in the US underscores the limitations of current prevention efforts. So does the fact that 2 to 3 times as many people become newly infected as who start treatment worldwide.

New efforts are needed to stem the growing tide of new HIV infections. While no one is calling for an end to older interventions ? like condom promotion and needle exchange ? new methods are clearly needed.

Recently Project Inform added prevention to our mission. Bringing our 20-plus years of expertise in drug development and treatment activism, we will focus on innovative prevention efforts that have a real chance of helping reverse the troubling spread of HIV infection. Two areas we think hold particular promise are the use of HIV drugs for prevention, called pre-exposure prophylaxis or PrEP, and earlier HIV treatment to reduce community level viral load.

Fauci highlighted some of the successes: reducing mother-to-child transmission and needle exchange. He also talked hopefully of PrEP, microbicides and vaccines. While the sense of frustration with persistently high infection rates is palpable, we can and must use this to create a renewed sense of urgency and embrace creative and innovative approaches to HIV prevention.

Vaccines

?When asked why we don?t have an HIV vaccine,? Fauci stated, ?I say, HIV is very different than other microbes.? This seemingly simple statement contains some of the truly vexing issues that have hampered the development of a vaccine to prevent HIV infection.

The single biggest hurdle to overcome is the lack of an adequate natural immune response against HIV in most people. Vaccines work by tricking the immune system into mounting a protective immune response. Because virtually nobody is known to generate such a response against HIV on their own, researchers must continuously hunt for the immunologic keys to controlling HIV.

While no magic bullet has been yet found, there are some promising developments. Fauci cited two papers published in the past year or so where researchers reported significant progress toward identifying potential targets for neutralizing antibodies, the gold standard of vaccine

development.

This news is particularly welcome right now, in the aftermath of the failure of the Merck vaccine. This widely reported setback reverberated throughout the HIV vaccine world and led Fauci to shut down a large trial of a different vaccine that was built on the same scientific basis.

While some despair at the prospects of ever developing an effective vaccine against HIV, Project Inform supports ongoing, targeted and strategic research toward this end. Scientific progress is often fraught with setbacks and detours. We cannot turn back; however, the need for a vaccine is imperative. Our strength of will needs to match the staggering need for a vaccine.

And finally the cure
Perhaps the most important part of Fauci?s talk was his utterance of the word, cure. After years of virtual silence on the prospects for an outright cure for HIV, there?s real movement in the search for a cure. As Project Inform?s founder Martin Delaney commented, ?It?s very important that someone of the stature of Tony Fauci is now emphasizing the critical importance of finding a real cure for HIV and not just settling for lifetime maintenance therapy. A few years ago, such a statement was considered heresy. People just didn?t want to accept the fact that treatment, however effective, is no bed of roses and can never fully overcome the problem of drug resistance.?

Back in 2004, Project Inform correctly identified cure-focused research (along with microbicides and PrEP) as one of the most important areas of HIV research. At the time, few if any major HIV researchers publically held out hope for curing HIV infection, seemingly content with the successes of lifelong maintenance therapy.

To help frame his short, but powerful discussion on the prospects for a cure, Fauci laid out two types of cures: sterilizing and functional. A sterilizing cure is synonymous with ?eradication? or successful elimination of every viral particle from the body ? similar to what has been achieved in some people with hepatitis C. This kind of cure has long been thought of as the only real cure, because of HIV?s ability to persist and replicate even after a decade or more of fully suppressive drug therapy. The thinking is that the virus is able to hide out in sanctuary sites and repopulate the body with circulating virus as soon as drug therapy is stopped.

As Project Inform recently wrote about, this thinking is not necessarily correct. While a truly sterilizing cure is certainly desirable, it may not be necessary. What may be needed is what Dr. Fauci called a ?functional cure,? or the ability for an HIV-infected person to live and be healthy long-term without the need of drug therapy.

Fauci proposed a potential model for such a cure that would involve very early and very aggressive HIV drug treatment, possibly along with HIV-specific immune based therapies. In his mind, the best chance for such a cure would be to begin treatment at the earliest possible moment, possibly within weeks of infection.

This paradigm would only work for a small number of people, which Fauci readily acknowledged. People would need to be diagnosed very soon after infection and have access to the aggressive therapies Fauci mentions.

Nonetheless, it would be truly groundbreaking to find a durable cure for anyone living with HIV. Beyond the obvious benefit to the people cured, it would almost certainly point the way toward better control, if not outright cure, of HIV infection for everyone else living with HIV.

While Project Inform has been advocating for more cure-focused research for some years, the impact of Dr. Fauci?s talk should not be underestimated. As Delaney put it, ?This is the first time a public official has raised the question of whether it will be possible to provide lifetime therapy for tens of millions of people. As Fauci noted, ?It?s one thing to provide crash treatment programs, but another altogether to sustain them for a lifetime for tens of millions of people.?

In a recent op-ed in the International Herald Tribune, award-winning writer Laurie Garrett called the HIV activist and scientific community to task for growing complacent in the face of lifelong drug therapy and all but abandoning the ultimate goal of a cure. As this writer said here, Garrett missed the mark in some of her comments, but also hit on some important truths ? most notably that for all of the very real progress we have made in treating HIV, the current paradigm is simply untenable. Having a figure as important as Dr. Fauci calling for and talking hopefully about the prospects for curing HIV infection should provide a great boost to this field. Project Inform welcomes Dr. Fauci?s comments and commits to cure-based research advocacy, until there is a cure.

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