RealHealthNews
Real action and research

The newsletter of real action and research • No. 4 • March 2006

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> Research for change

Seven ways to heaven

From local African research to Indian pharma's aim at a "five-billion" – person market, to radical R&D proposals to the World Health Assembly: what's happening to world health research?

SUMMARY

In a series of interviews, features, news and papers, over the next two issues *RealHealthNews* reflects on seven strikingly different ways health research is now being tackled, in and for developing countries.

Would you have predicted ten years ago that in a decade there'd be so much excitement and variation in research on developing country health as there is today, from Big Pharma eyeing the market to NGOs using research for evidence? We certainly wouldn't, so to get a better feeling for what's happening, *RealHealthNews* is taking an inside look at just a few of the strategies at work.

We begin at the frontline of health for the poor, and that's certainly where you'll find **Nduku Kilonzo** (page 3). Research Director of Liverpool VCT and Care, she studies the performance of government HIV/AIDS testing and care teams in Nairobi, working directly with their clients. But she also keeps a close eye on the health bureaucracy and government in Kenya, and international HIV/AIDS programmes and policy, and links research directly with helping health system managers effect real change.

Responding to the challenge of last year's Indian patent law, which respects international intellectual property and so puts generics companies continuing on page 2 >

"I'm so happy that I'm alive again" says Anthony Mpundu of Zambia, on ARVs and now able tend his fields. "I want to know for sure that I can take ARVs my whole life, even when I'm old."

> in doubt, **Smita Piramal** (page 6), Director of one of India's fastest growing indigenous pharmaceutical companies, tells *RealHealthNews* she's aiming for the market of the "five billion people in the world who do not have access to [high-price] drugs". And she's doing it with cutting edge research. Maneesh Nerurkar, Head of Pharmaceutical R&D at her company is one of her "acquisitions", an example of the "reverse brain drain", in which developing country scientists are returning to middle-income countries to create a new world of research back home. His objective is to create a "mini-Merck", to help the economic growth of India. While new Indian molecules will certainly be cheaper for the coming trillion-dollar middle-class Asian pharmaceuticals market, will the real health needs of the poor be met? The question is open.

Then **Regina Keith** (page 13), Global Health Advisor for the charity Save the Children – and an Editorial Advisor to *RealHealthNews* – tells us why she spends two-thirds of her time on research and evidence. Keith's approach represents a growing trend for major NGOs to turn to research to strengthen their advocacy. She has a strategic vision, that clear, objective evidence on successful, government-funded health systems can change global policy on user fees and health insurance. So she is helping to find that evidence across the world by uniting local and respected Western research institutions.

And in a paper (p. 14) **Jamie Love**, Director of the Consumer Project on Technology (CPTech), takes a dramatic new angle. Indirectly, he's been feeding WHO's own debate on health R&D. He argues passionately that pharmaceutical companies are far from the most efficient way to create health products for the world, and proposes a global health R&D treaty to revolutionize health R&D funding and intellectual property. So for us he takes stock of the January 2006 Executive Board meeting of WHO, which after submissions by Kenya and Brazil has promised fundamental debate on something close to the CPTech line at this year's WHA.

In the next issue, in time for WHO's World Health Assembly, we look at change in some of the more familiar bodies in R&D for health.

Lakshmi Sundaram of the Global Forum for Health Research will review the now dozens of public private partnerships (PPPs) at work for world health. How are they doing? Are they facing a major problem with the looming cost of clinical trials? The jury is still out. Mike Harper of the Global Microbicides Project – which could create a tool of direct relevance to Nduku Kilonzo and so many women in Africa and elsewhere at risk of HIV/AIDS – reveals the Project's hand to *RealHealthNews*, and we'll also hear from Anna Wang at the Medicines for Malaria Venture about the state of their pipeline.

Then **Jamie Guth** of the long-respected Tropical Disease Research programme (TDR) will report for us TDR's brand new strategic plan, completed this February, which with its wide portfolio including some of the most neglected diseases, will keep TDR among the many new players like the PPPs and the Bill and Melinda Gates Foundation.

And finally **Robert Walgate**, Editor of *RealHealthNews*, will report on the recent appointment of Tadataka (Tachi) Yamada, the present Chairman of R&D at GlaxoSmithKline credited with a revolution in the company's fortunes, to direct the Global Health Programme of the Bill and Melinda Gates Foundation, and on what it might mean for both the Foundation and GSK – whose commitment to TB, HIV/AIDS and malaria has, up to now, been significant.

Plus on later pages of each issue and on our website we cover some of the most important news, including in this issue: with the fatal H5N1 bird flu strain already in Nigeria, the extraordinary prospects for a genetically engineered bird flu vaccine (tuned swiftly to whatever pandemic human strain may hit); and the striking decline in HIV infection rates in parts of Zimbabwe (attributed to a change in sexual behaviour). ■

BRIEFS

MALARIA DEVELOPS RESISTANCE TO ARTEMISININ

The first frightening signs of resistance to artemisinin, the saviour among malaria drugs, has arisen in malaria strains in Senegal through a mutation in a single gene, whose expressed protein SERCA-PfATPase6 appears to be the drug's target. Single-drug artemisinin preparations were in uncontrolled use in the area. WHO has called for an immediate halt on their manufacture and use, and an increased focus on artemisinin combination therapies – which, however, remain too expensive for most users. ■

TB RESEARCH FUNDS "TO TRIPLE"

"During this next period, we'll triple what we've spent [on TB]", Bill Gates announced at the prestigious annual meeting of the World Economic Forum in Davos, Switzerland, last month. "In the past, [the Gates Foundation] has spent US$ 300 million... So we'll spend, during this period, over US$ 900 million... That's money that goes to partners like the Foundation for Innovative New Diagnostics, the Global Alliance for TB Drug Development, that's already got some candidates pretty far along. And then the Aeras Global TB Vaccine Foundation, which if that was fully successful, would really change the disease in a dramatic way" Gates said. His statement refers to the next decade, 2006-15, of the new Global Plan to Stop TB, announced at the same meeting by Marcos Espinal, Executive Secretary of the Stop TB Partnership. The Plan appeals for US$ 56 billion over the next 10 years, of which US$ 9 billion would be investment in research and development for new drugs, diagnostics and vaccines. ■

› Research for change

From local to global: action science in Nairobi

Know the bureacracy, problems and politics of health – and know the frontline of health care. There's a challenge for science, and it's being met in Nairobi

SUMMARY

Research bringing intimate knowledge of clients and their care in HIV/AIDS clinics, and of the bureacracy, politics and needs of national and international health government – is making Liverpool VCT and Care a scientific force to be reckoned with. Nduku Kilonzo explains.

Nduku Kilonzo is Research Director of Nairobi's Liverpool VCT and Care, a HIV/AIDS care facilitation and research organization – which began as an operational research project in voluntary counselling and testing (VCT) the Liverpool School of Tropical Medicine. Kilonzo's speciality is gaining evidence on the role of gender and rape in the AIDS pandemic – and even more powerfully, changing health policy and actions in response to her results. But how do she and Liverpool VCT do it? Here she spoke to Robert Walgate, Editor of *RealHealthNews*, in Nairobi.

NDUKU KILONZO: "We don't do biomedical research – there are already enough people doing that very well, from KEMRI to CDC! But there's a neglected niche, where we work – operational research.

We start by looking at what's required at policy level – which we learn from discussions, interactions, and meetings with people at that level; and then by studying our own programmes and services. Every year we do an internal assessment, and we look at what are the specific unmet challenges and gaps. So we talk to service delivery people, and government people we work with; and we talk to the programme managers, find out what people think, feel and see – even their predictions for the future.

At service delivery level we look at counsellors, the front-line staff who actually sit down with clients, patients, on a day-to-day basis, and provide a service. At programme level we talk to managers, not front-line providers but ones working very closely with them, facilitating their work.

At policy level I'm talking about governmental partners, and people who work with them. In fact our sense of being, our raison d'être, at Liverpool VCT, is to strengthen our governmental partners, so they in turn can strengthen the national response in HIV/AIDS prevention and care. We don't have VCT & care services of our own – we work with the government VCT and care services.

› RHN: So the idea at the research end is to provide solid evidence that can help the reformulation of policy…

NK: Yes. And practice! We use our research to influence both practice and policy. Our own practice and government practice, in terms of setting standards for service delivery and so on.

› RHN: How do you actually use research to change policy and practice? Obviously you can do it in Liverpool VCT, but how do you make change in government?

NK: You have to audit government structures to see where you can best locate your interactions and try to place your influence. For example, when we were doing out post-rape care work, when we started we didn't have a clue who was mandated [in government] to work on sexual violence. Eventually we found the right people in the division of reproductive health in the Ministry of Health. So we went there and asked if this was part of their work, is this what you should be doing, and so on – and once we'd begun to engage with officers in the division we were able to talk to them about the directions we thought the government should be taking, and saying how we can support your department or division.

› RHN: On the face of it this is like NGO lobbying. But the fact that you've done research, that you can write down evidenced papers – is that important?

NK: It's one of the most important things! And this is why Liverpool VCT is working this way.

› RHN: So tell me why it's so important. You interact with the bureaucrat. What happens?

NK: While you are interacting, even bureaucrats will ask questions! Why should I do this? How is it going to

continuing on page 4 >

> help me? What use is it? And what is the cost? What does it mean for me? Unless you've got some sort of evidence, indicators, benchmarks to say, 'actually we have tried it and it doesn't work the way you are doing it, it works another way – this one, points 1, 2, 3'. If you are responding to national gaps, you are usually responding to something that's already done, but there are challenges. So you are not coming in from nowhere.

› RHN: It's important therefore that you include the costs in these studies?

NK: We don't do it all the time, and I have to admit that's been one of the biggest challenges.

› RHN: Because at the political level that's a crucial issue isn't it – so I spend my money here or here?

NK: Yes, certainly. So we are being asked right now, 'you've given us this very good model for post-rape care, and how to scale it up, you've proved it works, we've seen it working – but look, you've spent X amount on about 800 survivors in the last two years – what does it mean for the government?!

So right now we are hoping to begin a cost study of that this Spring. And I think it's going to inform international policy as well, because there's no study like this for sexual violence interactions anywhere in the world.

› RHN: Have you any evidence on the proportion of HIV infections that are caused by rape? Would it be good to have some figures?

NK: Certainly! Because I was with a nursing NGO in a Nairobi slum village just this morning and they were telling me that they felt that quite a lot of their cases were caused by rape, but of course they had no figures.

It's something we all hypothesize about, at the global level, but it's going to be very difficult to get figures.

"To what extent are you an advocate, and to what extent are you a researcher who's getting your research used? It's a very delicate grey area."

› RHN: There's privacy and stigma and shame...

NK: Yes, and even if you look at trauma to the vagina or multiple penetrations or perpetrators, but putting all those factors together to calculate a risk is hard.

› RHN: To come back to your influence on policy, your studies are local, interacting directly with your government. But do you agree that there's another role for local research – validating locally international studies proved elsewhere, so bringing them to governments' notice? Do you do any of that?

NK: Because it seems to me that so often we get some breakthrough in the international journals, even social interventions like home-based care of malaria, which everyone says is immensely successful, there's a big noise in the media, but then it's all forgotten – and maybe just adopted in the researcher's home country, if he or she is lucky enough to be well-connected. But maybe if there were local studies, showing that this intervention is relevant to your own administration, these successes would take wider root.

Yes. And I think it goes both ways. It's important to localise results, and it's equally important to be able to use local studies to influence international policy – it should go back and forth.

› RHN: So how do you do that?

NK: Have great result, I suppose! That's one way of doing it! But also it's a matter of identifying the issue. When I look at national gaps, I prefer not to look at them from a very closed perspective. We have a huge list of questions to study, about eight pages of them! So one key thing to help us choose has been that we do a lot of reading, we make searches on the international literature search. So

one of our criteria in selection is what resonates globally, what's the challenge for international HIV prevention and care?

› RHN: After all we are working in an international framework in terms of response, the three ones, the 3 by 5 – everything has some international pivot about which it turns. So you work locally, but you need to be able to resonate with that. So what's the way you do that? Is it to get in to the international journals?

NK: Yes! That's important. We have access to those.

› RHN: Through academic quality.

NK: Yes.

› RHN: But how do you get to the international policy agenda?

NK: I'm not sure that we have a clear strategy. We don't. Except that in sexual violence we've been able to strategize for international policy, once we'd realized that what we were doing was important for that. So we began to feed a lot of our results back.

› RHN: To whom?

NK: To WHO – to the gender and HIV/AIDS group, to the gender, women, and health group.

› RHN: So this was quite apart from the publications.

NK: Yes. And word got around and we began to be asked questions.

› RHN: And you speak at meetings…

NK: Yes we do quite a bit of that! And currently we are doing quite a bit of work with WHO as part of the team doing international guidelines for PEP [post-exposure prophylaxis, to try to stop or slow an early HIV infection, such as in rape]. We're working on international guidelines for care and support of violence survivors. And once we had the call from WHO, we started to think what evidence we need to inform the policy-making.

Researchers? "I have to be honest! We create them! It's a matter of looking at interest, intelligence… We advertise."

› RHN: Aren't there very few academics willing to do this kind of research? How do you create the research team in Kenya?

NK: I have to be honest! We create them! It's a matter of looking at interest, intelligence… We advertise. We've not been a big research institution with huge research grants. Which is something we are just beginning to think about, realizing we need a clear research strategy and so on; but so far we've advertised for mid-level, not highly-paid, researchers, and got people like graduates, people interested in reading, and people who have a basic idea of what is going on in HIV prevention and care, from an academic perspective. That we find out at interviews.

› RHN: You have many applicants?

NK: Applicants we have to cut down there are so many! Many are people who've been out of university for two or three years in a first job, and want to do something interesting. And once you've made your selection, you try and make researchers out of them!

› RHN: Do they have a career path, a path out into research elsewhere?

NK: We are too young to think of that! But I got my own PhD through that. I came in as a researcher, did my first piece of work, got into a PhD programme…

› RHN: No kidding! So where did you come from?

NK: My first degree was in education – I'm a teacher by profession. And I was employed as a research assistant just after college and thought 'that's interesting'! I had a huge interest in gender issues, and I moved to UNDP, and in everything I was always looking for that little bit of research to do. Then Liverpool VCT was a lucky break for me because they had a job for a research student on gender and health.

Now we have two huge studies in mind, and are looking for more research students and funding.

› RHN: What studies are they?

NK: One is looking at HIV counselling and testing in diagnostic settings. So we aim to develop systems and protocols that can inform government. Because it's a mess, to say the least, very ad hoc. So it's a huge challenge, but we are working quite closely with NASCOP, the National HIV/AIDS and STD Control Programme, who are very interested. Continuing on page 16 >

READ ON

Liverpool VCT & Care, Kenya
www.liverpoolvct.org/

Liverpool School of Tropical Medicine
www.liv.ac.uk/lstm/

Ministry of Health, Kenya
www.ministryofhealth.go.ke/

Using gender analysis to build voluntary counselling and testing responses in Kenya. Nduku Kilonzo et al. *Transactions of the Royal Society of Tropical Medicine and Hygiene* (2006) 100, 305-11; Epub 2005 Oct 7, *Elsevier* Full-Text Article

Bypassing districts? Implications of sector-wide approaches and decentralization for integrating gender equity within district-level health systems: experiences from Uganda and Kenya – by Nduku Kilonzo et al, 2005, Oxford University Press in asssociation with the London School of Hygiene and Tropical Medicine.
www.leeds.ac.uk/ngotu/Gender_SWAp_Uganda.pdf

Conceptualising vulnerability to sexual violance and HIV: implications for practical responses: address by Nduku Kilonzo to a Satellite Workshop of the Global Forum for Health Research, Forum 7, December 2003.
www.liv.ac.uk/lstm/vha/06kilonzo.pdf

› News analysis

New HIV infections in young women fall by half in East Zimbabwe

Change in sexual behaviour is the cause, and was in turn induced by education, claim researchers

SUMMARY

Did information, education and communication on HIV transmission and risk – or the death of relatives and friends – cause a significant change in sexual behaviour, and a dramatic fall in new HIV infections, in Eastern Zimbabwe?

› by Prakash Khanal

Significant changes in sexual behaviour among young Zimbabweans are causing a dramatic decline in HIV infections, according to researchers in London, South Africa and Zimbabwe, in a paper published in *Science*.

According to the study in Eastern Zimbabwe, over the five years 1998-2003 HIV prevalence associated with sexual behaviour fell 49% among women aged 15-24, and 23% among men aged 17-29. HIV prevalence was less among more educated groups. Sexually experienced men and women also reported reduction in casual sex by 49% and 22% respectively. Men also claimed to be using condoms and having fewer partners.

The researchers considered several other factors that might account for the large fall in HIV rates, such as migration or death, but remain convinced that sexual behaviour change is the cause.

"The measures of risk behaviour were all recent – the numbers of partners in the last year, and recent casual partners – and were compared at two time points," Geoff Garnett, one of the authors of the study, Professor of Microparasite Epidemiology, Department of Infectious Disease Epidemiology, Faculty of Medicine at Imperial College London, told *RealHealthNews*.

"We did consider whether differential mortality could explain the change by looking at reported number of partners (in the first round) amongst those in the population who subsequently died. This could explain some change but not very much".

Garnett is certain that there have been definitive changes in sexual behaviour, including increasing use of condoms during casual sex. "If people are aware of the risk of HIV infection and are empowered to decide whether they enter casual sexual relationships or not, then they can have fewer partners," he said.

Although the study did not identify the exact causes of behaviour change, it indicates the changes were observed equally in areas with or without focused HIV/AIDS interventions. This could mean that information and knowledge about the epidemic is now widespread. Many people have been affected by the premature death of one or both parents and of friends.

"Zimbabwe's well-educated population and good communications and health service infrastructure could have facilitated HIV prevention" the *Science* paper concludes. "HIV prevention activities in Zimbabwe have included early control of sexually transmitted infections, social marketing of condoms, voluntary counselling and testing services, TV and radio serial dramas, and the activities of the Zimbabwe National AIDS Trust Fund."

Garnett told *RealHealthNews* "It seems that information, education and communication within an affected and mobilized community is ultimately paying off". Helen Weiss, senior lecturer, MRC Tropical Epidemiology Group at London School of Hygiene and Tropical Medicine, also believes that focused interventions, with the help of radio, television and other communication media, as well as government agencies, are working. "This success, however, should give us the reason to work even harder," she said Weiss.

Weiss and Garnett say that successful information campaigns empower the people to make informed choices, and lead to behavioural change, and should be applied in other HIV prevalence hotspots. But everything depends on the communities acknowledging the risks of HIV and AIDS, they say.

Other countries that have recorded a decline in HIV incidence and prevalence in the past, arguably due to intensive HIV prevention programme and medical interventions followed by documented changes in reported sexual behaviour, are Uganda and Thailand. Zimbabwe can also now be added to the short list of countries that have seen substantial declines in HIV prevalence. The researchers say there is also growing evidence of declining HIV prevalence in Kenya, Burkina Faso, Cambodia and Haiti. ■

READ ON

HIV Decline Associated with Behavior Change in Eastern Zimbabwe, February 2006, *Science*, Vol 311, pp 664-7

› Research for change

Mumbai pharma plans new drugs for all

Nicholas Piramal, India's number two pharma company, is ignoring generics and relying on R&D. First in the pipeline: a new low-cost cancer drug

SUMMARY

When the Director of Nicholas Piramal speaks of a global market, she means it – drugs affordable for five billion people. Moreover she's reversed the brain drain, and attracted successful Indian research scientists back home from Western Big Pharma. She aims to use R&D to make the first totally Indian pharmaceutical. Here *RealHealthNews* talks to her, and to several of her staff, including the Head of Pharmaceutical R&D – recently recruited home from Merck. We ask him to tell us his story, and with him and others investigate the plans for R&D at his new company.

Maneesh Nerurkar and Ramani Aiyer.

Nicholas Piramal India Limited in Mumbai – an outgrowth of a famous old textile business that has extensive real estate throughout the 'maximum city' – is forging a new path for pharmaceutical R&D in India: for Piramal it won't be cheap generic copies of molecules researched and developed in the West, but brand new chemical entities for a foreseen multi-trillion dollar Asian pharmaceuticals market – and for poorer markets worldwide.

Already Nicholas Piramal has reached the number two position in Indian pharma, behind the massive generics company Ranbaxy, and even Ranbaxy is now stressing indigenous R&D – in the face of last year's Indian patent law which brings India into line with the West for all new drugs.

So what's happening? Why are Indian scientists returning? And with some of the world's poverty literally on its doorstep, is Indian pharma now about to turn its back? To get an inside view, *RealHealthNews* decided to paint a quick sketch of R&D at Nicholas Piramal.

We first talked in Mumbai at Forum 9 of the Global Forum for Health Research to Swati Piramal, MD, graduate of Harvard School of Public Health and Director of the company, about her goals. Totally upbeat about the potential for Indian pharmaceuticals, she predicted she could create a new cancer drug – called NP-276 and already in Phase I/II clinical trials in Canada "with no bad news yet" – for US$ 50 million, one tenth to one twentieth the going rate among multinationals of some US$ 500 million to US$ 1 billion.

If it succeeds, the market price will be correspondingly low too, "lower than everyone else in the world", she told *RealHealthNews* later (Februrary 2006). "Of course there are lots of ways you can do the accounting, including the costs of failure, and we haven't yet succeeded making a new drug go global – but that's our goal. I'm willing to be wrong by 100%, so on the outside it will be US$ 100 million."

So will such a drug be available therefore to a wider, and poorer, market? "Exactly" said Piramal. "We are saying that there are five billion people in the world who do not have access to drugs that cost US$ 1 billion to create. We feel they are our market." Continuing on page 8 >

> How can she do it? She is creating a "reverse brain drain" among scientist émigrés, she said, and could offer scientists better conditions of work and life than in the US.

One of those returned émigrés is Maneesh Nerurkar, Head of Pharmaceutical R&D. We talked to him in a beautiful laboratory, full of modern art. We might have been on the West Coast of the United States, with the Pacific rollers nearby, but this was Mumbai, and the ocean was Indian.

> RHN: What's your story, Maneesh?

MANEESH NERURKAR: I grew up in a small town in India called Indore in Madhya Pradesh – right smack in the centre of India between Bombay and Delhi. I was born into a rather affluent family – with the luxury of libraries, international travel and all that. So I was very lucky. However my parents had begun quite poor, and my father had managed to go to America to study, and returned to become a pioneer in chemical synthesis in India.

The whole 'active pharmaceutical ingredient' thing in India is due to some of the efforts my father made in the 1960s. India is probably [the world's] leading manufacturer of drugs – but not in the finished dosage form, in chemical ingredients. And he helped make India realise that it can do this as a business… He and Ranbaxy's owner were colleagues for a time.

So even though I grew up in a small town I was exposed to all these modern ideas. But they had down-to-earth values and made sure we children were not overwhelmed by the money and become materialistic. In fact I always want to be a paediatrician, and I studied hard, did well and went to Indore medical school. But there was rampant nepotism – in the first examinations, all the top people were somehow related to the professor. It was really a bad situation - I was extremely frustrated. But my father said if you want an absolutely unbiased academic environment, try America. So I quit medical college and studied pharmacy, and fundamental pharmaceutical chemistry at Kansas, which then and perhaps still is one of the foremost institutions in that field. My belief is that if you understand physical chemistry then everything else becomes relatively easy!

So I then worked at Merck, in West Point Pennsylvania – it's had a lot of bad press over Vioxx [a controversial osteoarthritis drug] but in my opinion it's absolutely the best pharmaceutical company in the world.

"We are saying that there are five billion people in the world who do not have access to drugs that cost US$ 1 billion to create. We feel they are our market"

SWATI PIRAMAL

> RHN: Best in what sense?

MN: It has the finest scientists in the world; and even from an ethical point of view, their emphasis on safety was so high that we used to say "if it makes it through Merck, it will make it through the US Food and Drug Administration (FDA).

So I really flourished in that environment. You are surrounded day in and day out by really really smart and intelligent people, far smarter than you are! So you can't stagnate. But all through that I knew that I wanted to go back to India and do something for India. It was only a question of timing.

> RHN: Was that an idealistic motive?

MN: It was more to do with giving something back to the country. I'll be honest, it was not to take care of the poor or anything like that. I just want-

Swati's first song for India

Swati Piramal has made a music video of a 100-year-old song praising science by Rabindranath Tagore, the famous Bengali writer. She had the text translated into Hindi and subtitled in English, and produced an all-dancing all-singing version, worthy of Bollywood.

Tagore wrote the song for his great friend and Indian physicist J C Bose, whose name is written into the language of physics, as every particle of a force field – such as light itself – is said to be a "boson".

In Piramal's version of Tagore's song, the Indian flag is waved prominently, the words "victory, victory, victory" are prominent, and the poem comes to represent the coming flowering of Indian R&D, eliminating ignorance - and finding new means to help people "at the bottom of the pyramid", as Piramal puts it.

"This was my first music copyright" she said, laughing. "Every scientist who hears it says 'this is for the world'. But I'm donating it to the President of India. ■

ed to do something good for the country, because America has everything. Obviously selfishly there's a lot more one could do there, but I'd always had India in mind. The only thing that held me back was that I thoroughly enjoyed working at Merck!"

› RHN: And the salaries are good too.

MN: Well these days, they can be reasonably good here too, for some positions. That was not the main consideration. Because I could have changed jobs in America many times and got higher salaries, but the work environment at Merck was fantastic. Every day I wanted to get up and go to work!

› RHN: So you also needed an exciting place to come back to. How did you find this post at Nicholas Piramal?

MN: I asked my father to e-mail me a list of companies. He did so – and this company wasn't one of them. Because it's a relatively new company, started in 1988, and all the big companies he remembered were from much earlier.

So I wrote to them, and came and interviewed with most of them. I wanted to stay near Mumbai, as that's where my parents were. I was literally about to sign with one in Mumbai, when I got a call from Nicholas Piramal. They'd heard of me from American contacts. I said I think I've already decided on a post. But they persuaded me to meet the Chief Scientific Officer (CSO), Somesh Sharma, and was heavily impressed, unbelievably impressed by him. He'd lived in the US for 35 years, so that made it easy – he understood my style of working, and my thoughts, which would most likely be very different from people who had worked only in India: it's a very different work culture.

Secondly I could see in half an hour that he was very very bright. You need to respect your boss for something. But I said I'm committed to go to this other post, it's difficult for me the change. He insisted, but I said no. Then when I got home I got a call from Ajay Piramal, the Chief Executive Officer (CEO) himself, saying he wanted to meet me. I was so flattered that the guy who runs such a huge organization values this position enough – obviously he didn't know me – that he makes sure he gets someone his CSO is saying is the right person.

So I met him the next morning, and one of the things I liked was that he laid immense pride and value on becoming the first to put a purely Indian molecule on the market. And of all the things he said this one sentence grabbed me more than anything.

The second thing he said that I remember was to name the scientific advisory board – I didn't know them, but he was proud of them and their thinking, and one was an Albert Lasker Medical Research award-winner etc., and this was so different from the usual Indian approach – where the boss is the one making all the decisions. But he said no, everything is being driven by the CSO, reporting to a scientific body. So it is all very neat, clean and clear. So I liked that also.

"India hasn't had a history of discovery for the last 30 years. That was the result of our 1970s patent law."

Money we didn't talk about! But let me be clear, you need money! Mumbai is not a cheap place to live. Housing is very dear and many other things are rising by the day. Some things cost more than in America! But I was not seeking more money. They matched the other company's offer. If one wants to do that one can go on forever. Every company wants to pay you five Rupees more than the other.

The hardest job was to get education for my daughter. But Swati Piramal personally gave us a lot of useful advice and got me in touch with the best schools in Mumbai. I valued her empathetic approach. So I joined.

Now, every day I hope that I can reproduce the Merck culture here. That's what I tell all the people who report to me – that I want to create Nicholas Piramal as a mini-Merck.

Investing in people is very important. We expect to reach 400 people in 2006. 10% of our scientists have experience abroad.

› RHN: How did you build the team?

MN: Somesh [the CSO] has concluded it's very difficult to get biologists in India. The hurdle is not chemistry at all, it's biology.

Ramani Aiyer, Head of Strategic Planning, R&D, expands on this:

RAMANI AIYER: Anything that's development type work, whether it's chemistry or pharmacology or the pharmaceutical R&D process, I think we have pretty good strengths. But what we don't have is strength in [biological] discovery. So discoveries where you really have to understand biology are all challenges.

And the reason is that India hasn't had a history of discovery for the last 30 years. That was the result of our 1970s patent law. Until the 1970s the country was dominated by [foreign] multinational companies, and there was no indigenous pharmaceutical industry. So the government decided to develop it by banning product patents and recognizing only process patents... That's primarily responsible for the growth of Indian pharma. It was a government strategy.

However, this strategy killed innovation, except in processes, said Aiyer. But now the revision of India's patent laws in 2005 to include intellectual property in products will bring R&D to the fore, he believes.

RA: It's really exciting. If you look at oncology, our first molecule, NP-276, is a CDK4 inhibitor, Continuing on page 10 >

> which inhibits the cell cycle. The neat thing about this is that it is very specific to cancer cells, which is the new paradigm. The target in inflammation is TNF alpha, but what we're doing here is that rather than looking at TNF alpha blocking, like Enbrel and Remicade, we are looking at inhibition of TNF alpha production. And we are looking at small molecules, not biologicals.

Then in diabetes – we want to look at very specific, focused insulin sensitizers; and in infectious diseases we are looking at an exciting antibacterial [which is active against MRSA, methicillin-resistant Staphylococcus aureus], we have an exciting antifungal too but we can't do everything at once.

And we've in-licensed a technology from Canada to make vaccines. There are several components in a vaccine; the antigen of course, which is the immunogenic portion; we also need an adjuvant, which boosts the immune response; and we need some vehicle in which this thing can be delivered. All are very important. This novel technology has the characteristics of both a vehicle and a very good adjuvant.

> RHN: So as well as basic discovery you could also in-license an antigen and put it in this vehicle.

RA: That's right. So we are sourcing for antigens. Marry the two, and we've got something.

So that's our integrated drug discovery approach. We are not in the business of target identification and validation. But we do have chemistry, isolation of products going into lead optimization, and a strong cheminformatics group, with a couple of mathematicians who trained in maths and statistics but dabbled in chemistry. Our rigour of analysis comes from them, applying computational techniques – in-silico techniques – to look at chemicals and predict how they'll behave on a particular target. And we have pharmacology, with all the pre-clinical studies.

We have about 12 different programmes, and I expect several entities to be in IND territory [the step before clinical trials] in 2006.

We also have a lot of collaboration. There are a lot of pockets of excellence in Indian academia, and we want to tap into our own backyard – because clearly we can't discover everything ourselves.

So we have a collaboration with a university in Chennai, looking at Southern Indian medicinal plants for anti-inflammatory drugs. Likewise we have very exciting work looking at novel targets in antifungals. We're looking at DNA in fungi that won't overlap DNA in humans, and therefore probably won't be toxic, if you make a molecule to inhibit it.

I said we don't do target discovery but this is an exception. So we are dabbling in serious biology by funding some of these academia – so over the next five years we are hoping to build some capability.

And we want to start an in-house teaching programme, to support post-graduate education. So we are talking to local universities about affiliation as a centre for PhD and post-doctoral programmes. So some of our senior scientists would become adjunct or affiliate professors, under whom people can do PhDs.

That way we can retain very bright people who join us for an MSc but then leave and go abroad to do a PhD. If we can offer that here we can retain them. We'll do the same thing with post-doctoral fellows. It's our contribution to the country.

Then in the laboratory, Sunil Deshmukh – a senior scientist responsible for microbiological activity – told RealHealthNews *where many of the new molecules were coming from: Indian flora.*

SUNIL DESHMUKH: We collect them from high altitude to ground level North to South, in altogether different climates, from hot springs, dung, rivers, marine water, historic monuments, anthills, mines – everywhere. I personally believe a lot of bioactive compounds will come from marine water.

We've already got 50'000 micro-organisms, 5'000 endemic plant extracts, 17'000 fungi – tropical countries are not well-explored for them, so there are many new species to find."

> RHN: Who collects these?

A lady colleague, Shilpa Verekar, spoke up.

SHILPA VEREKAR: We do – we personally go out. I'm from Madhya Pradesh, with experience of screening against micro-organisms, at Masters level. I dropped my CV in everywhere and was very lucky to get here. I think this is a fantastic environment to work in. You work on a lot of new things, the people are cooperative, from senior to junior there's transparency.

SUNIL DESHMUKH: Yes, you can approach our CSO without any appointment…"

SHILPA VEREKAR: "That's the best part. It's not your qualification or seniority that matters, it's what work you put in. Our CSO values people for their work. That encourages us." **RW** ■

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› News analysis

Fast computerized vaccine might protect against any pandemic flu

Revolutionary method promises human pandemic vaccine "within a month or two" of virus sequencing

SUMMARY

H5N1 bird flu now in Nigeria will kill chickens, and even some people, but it is not pandemic human flu. Nevertheless a pandemic may emerge anytime, anywhere – from a related virus created by its recombination with ordinary human influenza. Response needs to be fast, and now a new genetic method is claimed to be able to create a vaccine within two months of sequencing.

› by Prakash Khanal

Eggs. They've been the problem with existing influenza vaccines. They must be grown in chicken eggs, a process that takes half a year to a year to create enough vaccine for the world's usual winter round of 'flu.

But now a new methodology using computerized genetic manipulation promises a vaccine which "can be made quickly – within a month or two" Simon Barratt-Boyes, Associate Professor, Department of Infectious Disease and Microbiology, University of Pittsburgh Graduate School of Public Health, told *RealHealthNews*.

"It just requires the sequence of the influenza virus to be cloned into an adenovirus [one of the causes of the common cold]. And we can do this from scratch by synthesizing the gene from a published sequence of the virus taken from the computer," he said.

A variety of influenza viruses is now being sequenced at the rate of two or three viruses a day by the Institute for Genomic Research TIGR, by the Influenza Genome Sequencing Project at the US National Institute of Allergies and Infectious Diseases, NIAID, and by other institutions, so a pandemic virus should be quite swiftly sequenced.

"The genetic sequence of the influenza haemagglutinin gene [coding for the haemagglutinin surface protein] is then cloned into a replication-defective adenovirus which expresses the gene in immunized individuals," said Barratt-Boyes. Using the existing bird flu virus, "the vaccine also stimulates several lines of immunity against H5N1. The adenoviral vector is very immunogenic, and a single dose will induce a good immune response".

At least these are the results of trials in mice and chickens at the US Centers for Disease Control, which is collaborating in the research with medical researchers from University of Pittsburgh Medical Center. The work was published in the Journal of Virology in February.

Birds were protected from a lethal challenge with influenza virus, but small amounts of virus were still recovered from some tissues and the oral cavity. Whether this small amount of virus is sufficient to transmit infection to other birds is not currently known. A further concern is that many people have pre-existing immune responses to the adenovirus itself, which limits its effectiveness, so new stereotypes of adenovirus are being investigated to overcome this problem.

Before proceeding with clinical trials the researchers would like to know a little bit more about what causes protection in the animal, and whether it is antibody-mediated or cell-mediated.

Simultaneously they are seeking funding for safety testing in a Phase I clinical trial. According to Barratt-Boyce, if funding is received, they will begin locally with volunteers. Barrat-Boyce believes "there will be absolutely no risk as the adenovirus is completely safe, and the single influenza virus gene in the vaccine cannot cause disease. They will not be challenged with influenza".

If all goes well Phase I could begin and could be completed within six months. Phase II-III, determining the effective dose, and the actual protection against disease, would then take place in Vietnam, China, Thailand or Cambodia where bird flu is a significant menace to humans. Perhaps Turkey, Greece, Italy and now Nigeria, where H5N1 has recently been identified, could be added to the list.

If successful, this would then have created not just a human H5N1 vaccine effective against the current bird 'flu – which, remember, has only killed a few dozens of people and is not a pandemic strain – but a new methodology and principle for creating a true pandemic vaccine very quickly. But this would raise a fundamental point of principle, practice – and risk. Given the pandemic virus sequence, and the adenovirus construct, a vaccine could be made and in

Continuing on page 16 >

› Research for change

Research for free health

Regina Keith, Global Health Advisor at Save the Children tells *RealHealthNews* why this is a critical moment for research on health financing

SUMMARY

The NGO Save the Children hoped to use Sri Lanka as a global model to show the success of free primary health care – and researched and reported their case thoroughly. Still the world didn't notice. But they think strategically, and have new plans on how to turn research into action, with North-South "research coalitions" with Africa and Latin America getting to work as user fees are cut.

› RHN: with the Institute of Policy Studies in Colombo you researched Sri Lanka's success in bringing down child and maternal mortality – and reported your results in the document Bucking the Trend. But now you're moving research on what you call "socially just financing" into Africa and Latin America, and bringing in Western academia – what's going on?

REGINA KEITH: Did you know that in 1978 WHO's Alma Ata declaration on primary health care, calling for health for all by the year 2000, built on what Sri Lanka was doing?

Today, Sri Lanka is still resource poor, with high malnutrition rates, but without high mortality in children or mothers. So we looked at how they achieved that. We concluded that one of the reasons was that they prioritized health, and education, free – plus food – at the point of service. Sri Lanka was one of the few countries that didn't follow the 1993 World Bank model for economic growth – they continued with free inpatient and primary health care.

Now we aim to see if this model can work elsewhere. Several countries have ended (or are planning to end) user fees, and we want to use evidenced-based operational research to pilot alternate health financing mechanisms and measure what happens.

One interesting case study will be Bolivia – the new president, Evo Morales, has promised to turn their present approach upside down by unprivatising water services and making health services free at the point of access. They will use insurance: if you can buy insurance, you do; but if not, the government pays.

› RHN: Have they been influenced in this by what they know and have learned about Sri Lanka?

RK: Certainly they have been influenced by Cuba, which has followed a social justice model, and reaped health benefits. However that's a communist country, of course, so other things are different. We chose Sri Lanka as a case study as they have managed to achieve good health outcomes despite weak economic growth, high levels poverty and malnutrition, and even internal conflict [with Tamil separatists]. Even in the conflict areas, access to health and education is still free at the point of service.

So Sri Lanka could be a good model for Africa, where conflict is an issue in many countries. Although issues like transparency and gender equity are very different.

Donors like the UK's Department for International Development (DFID) have been working with countries like Uganda and Malawi and Zambia to make health systems work for all through health sector reforms. In Uganda, health service utilisation more than doubled after abolition of fees, with an increasingly decentralised drug budget and staff salary increases.

"Changes are happening now. We need to hit the ground running [with this research]. The need is immediate."

We've also been looking at countries like Madagascar, which abolished fees during the war, and had a boom in the use of the health system – which dropped again once fees were reinstated. But now they say they can't afford it. Then South Sudan is building a new set of policies, and does not want to use fees; but they too may not be able to afford free health care.

But last year the G8 group of rich countries pledged finance for countries wishing to abolish fees, with UK particularly strong on the negative impact of fees on the poorest.

› RHN: Everything you've been saying is deeply political – there are strong positions for and against user fees. But for you, what has research got to do with it?

RK: We hope to work with some countries to support research coalitions – linking ministries, NGOs and academics – ensuring countries get technical support for evidence-based programmes for operational research.

There's a big problem with the perception of aid effectiveness. If we can't show that aid has been useful…[in the future it may be lost].

What we need to do is to find out if [abolishing use fees] works! Is it a model for Africa? Changes are happening now. We need to hit the ground running. The need is immediate. We need to get to districts now, to do research, to measure impact, while helping ministries to ensure that children are immunised against deadly diseases and protected against dying from treatable diseases like pneumonia and diarrhoea.

› RHN: So you want to do operational research as the money goes in, and as policies are implemented.

RK: Exactly, and then see if the money's getting where it should, because one of the big challenges is money not getting to where it needs to go.

We've just secured funding to support health systems in one state in Nigeria. Working with someone like His Excellency Dr Eyitayo Lambo – Minister of Health in Nigeria – who understands economics and research, as he demonstrated in your interview with *RealHealthNews* – could ensure that evidence – based programmes are rolled out in other districts. We'll start in a district, and if it works in a pilot in that district (and Nigerian districts are massive, like countries inside a country), we could see if it could be transferred to the rest of the country.

To do that [at national scale] countries need a promise of long-term funding, with G8 countries following through with increased aid and debt relief. With technical support we may be able to change the present course for children in Africa and reach MDG 4.

"We're trying to operationalize research in Africa."

› RHN: And research, if it showed the pilot worked, could help to convince them…

RK: That's why we're trying to "operationalize" research in Africa. Take South Sudan, which has agreed they don't want user fees. Can we research with them to build new policies and effective alternatives to fees? In countries like Tanzania, we're looking at the systems they have right now, working with a national research institute, Research on Poverty Alleviation (REPOA).

Harvard University and other academies are also interested – as are donors. We want to study what changes in health financing mechanisms at district level are possible, in order to ensure the poor can access effective health services.

› RHN: But if Sri Lanka was your model, aren't there so many other positive factors there, that influenced their success, such as education levels? It's not obvious it will work elsewhere.

RK: That's why we need to do proper case studies in other countries! Take Botswana. In 1967, before they found diamonds, they decided to have free health and education. Then they struck lucky and the diamonds helped them to fund that. But they still have problems. Why? How do we overcome the bottlenecks and problems? That's why we need to look at countries like that as case studies.

And take countries like Uganda, which took steps that have had a positive impact on health, but now face governance issues and electoral pledges, which could lead to regressive decisions being made.

› RHN: What kinds of operational research do you want to see done?

RK: I'd like a mixture of ministries, communities, NGOs, national research institutions, and academic institutions and WHO. We need to address the present reality that sees less than 10% of research being spent on diseases of poverty – with less than 3% of that on health systems research. NGOs and civil society are often ignored in such coalitions. We need to combine NGO access to communities and strengths in qualitative research, with more normative research. We need to twin more institutions in the West with ones in the South.

And we will set up peer review panels, like you have at *RealHealthNews*. That panel would agree on the kind of baseline studies we'd do, read initial results, and help to put together an initial questionnaire, covering the breadth of issues and indicators we need to follow through. And they'd help with quality assessments mid-term and at the end, help to edit final reports and pull out the policy implications. And sometimes even come to the meetings! **RW** ■

READ ON

Bucking the Trend – analysis of Sri Lanka's free health provision
www.savethechildren.org.uk/scuk/jsp/resources/details.jsp?id=2326&group=resources&section=publication&subsection=details

The Alma Ata Declaration, December 1978
www.who.int/hpr/NPH/docs/declaration_almaata.pdf

Research and politics "need a marriage" – interview with Minister of Health Eyitayo Lambo, *RealHealthNews* No. 3, September 2005, p 15
www.globalforumhealth.org/realhealthnews/RealHealth_No3.pdf

REPOA
www.repoa.or.tz/about_us/about.php

Poverty, Inequality and Health: An International Perspective
David Leon & Gill Walt (Editors)

Save the Children
www.savethechildren.org.uk/scuk/jsp/index.jsp?flash=true

› Research for change

WHO to debate global R&D "framework"

› by James Love,
Director, Consumer Project on Technology, Washington

SUMMARY • *Square brackets – to enclose controversial text – now litter a resolution from Kenya and Brazil for May's World Health Assembly. The resolution calls for debate on a radical proposal to transform global health R&D, but the organization's Executive Board is pulling the punches. Nevertheless there could still be significant developments.*

On 27January, 2006, the World Health Organization Executive Board – a small group of states that prepares the programme for the coming World Health Assembly in May – agreed to forward for debate a resolution concerning a new "Global Framework on Essential Health Research and Development." The debate over this resolution is an attempt to involve the WHO in a new role of pro-actively re-shaping global policies regarding the support for R&D for new medicines. It is controversial.

First submitted by the governments of Kenya and Brazil, the original version of the resolution touched on a number of different aspects of the global system for supporting medical R&D, including topics such as the equitable sharing of the costs of R&D; the need for better priority setting ("needs-driven R&D"); the importance of both access and innovation, including follow-on innovation; various problems concerning intellectual property rights and trade agreements; and the promise of new "open models" for the development of medical science.

It called for the creation of a group of member states to consider proposals to establish a global framework for supporting needs-driven research, consistent with appropriate public interest issues, and for a variety of other measures that were designed to promote access to medicines and a needs-driven R&D agenda.

The 1 200 word version of the resolution that emerged from the WHO EB (EB117.R13) contained most but not all of the original ideas, but also a number of proposed modifications, including several that would weaken or change the direction of the resolution. There are now 32 areas where the text of the resolution is bracketed, including even the words "Global Framework" in the title, indicating divisions among the WHO EB members on the most important issues.

The existence of so many areas of disagreement raises questions about the degree to which the WHA members – the world's governments, represented by their ministers of health – can reach consensus on the proposal at all, or if they do, what the final product of negotiations will look like. Nevertheless it is a remarkable effort to fashion the landscape for financing R&D on new medicines, and if it is embraced, it could open the way for a new and important way of addressing medical R&D at the global level.

A Global Framework for Essential Health R&D

But what would a "global framework" for needs-driven health R&D actually look like? By definition, a framework is a "basic structure underlying a system." This could take many different shapes.

Brazil and Kenya's proposal for the creation of a working group of member states to consider the global framework would be a first step – a step toward multilateral negotiations, open to any interested country, to discuss and set norms about the appropriate level of support for medical R&D, and the creation of new mechanisms to address priority setting for R&D.

It could be a simple set of 'soft' norms, such as a suggestion, without enforcement, that a certain percentage of a country's global GDP or health care budget supports essential medical R&D.

It could also be a more formal obligation, such as an agreement or treaty that required members to directly or indirectly support medical R&D.

It could also include news mechanisms to identify priority R&D in areas of greatest need, opportunity or benefit, and incentives or obligations to address these priorities.

It could address issues of technology transfer and capacity building in developing countries.

Such a framework could be completely outside of and separate from other frameworks that support medical R&D, like existing provisions in trade agreements such as the WTO's TRIPS agreement or the many bilateral accords that touch on drug patents or drug prices.

But it could also be a model for an alternative and competing paradigm, based upon public health perspectives, that could eventually replace the older agreements, in terms of

determining who will pay for the costs of R&D for new medicines. The choice of the word 'framework' is general enough that any of these outcomes are possible. The resolution simply opens the door for discussions on these topics to start. It does not say how they will conclude.

The need for a new framework to support innovation

The resolution notes a number of areas where medical R&D is inadequate. Much of the emphasis is on areas of particular relevance to persons living in poverty, singling out for example the need for new vaccines, diagnostics, and medicines, including microbicides, for the treatment of AIDS, Tuberculosis and Malaria, as well as other illnesses that disproportionately affect persons living in poverty in developing countries.

But the resolution also addresses other concerns, such as the importance of the development of treatments for diseases that have small client populations (often referred to as 'orphan' diseases in the US or Europe), and more broadly, it notes that more than 70% of all new drug approvals are for medicines that do not provide incremental benefits over existing ones.

The resolution also makes reference to the importance of global public goods, such as the Human Genome Project, and other "open and accessible public research in advancing science and the transfer of technology."

The resolution recognizes the importance of both public and private investment in the development of new medical technologies. It states that intellectual property rights are one of several important tools to promote innovation, creativity, and the transfer of technology, but also notes the importance of "providing for a proper balance between intellectual property rights and the public domain," and "the need to implement intellectual property rules in a manner that is consistent with the fundamental right of every human being to the enjoyment of the highest attainable standard of health and the promotion of follow-on innovation." Concerns about access to medicine are mentioned several times.

Reconciling access and innovation

The resolution notes the need to "reconcile the public interest in accessing the products derived from new knowledge, with the public interest in stimulating invention."

Civil society supporters of the proposed resolution, which include a large number of public health, development and public interest NGOs, hundreds of well-known scientists, including several Nobel Prize winners, and many economists and other experts, see the resolution as a first step in a new approach to globalization that addresses the issue of R&D for new medicines as a public health matter, rather than strictly commercial concern.

The TRIPS accord of the WTO and the plethora of new bilateral and regional trade agreements that deal with drug patents and other measures that raise drug prices are seen as:

- raising barriers for access to medicine everywhere
- ineffective in promoting certain types of medical R&D, including investments in global public goods, or the development of medicines that are most relevant to persons living in poverty.

A new approach of focusing directly on the need to support R&D, with a realistic discussion of who will pay, is seen as a necessary step in addressing the legitimate concerns that the globalization mechanisms provide sustainable sources of finance for R&D.

By recognizing the importance of both public and private sector investments, and the need to also address market failures and priority setting, the new framework can be a better mechanism – one that helps rather than hurts consumer interests.

In the January debate over the resolution, most developing countries on the WHO EB supported the resolution. Unfortunately, most countries with annual per-capita incomes greater than US$ 10 000 were less supportive. The United States, Japan and the European Union (which acted on behalf of its member states) all sought a number of changes that would cumulatively reduce the resolution to a highly general appeal to provide more incentives for pharmaceutical companies to invest in neglected diseases.

These countries insisted on brackets on virtually every mention of global public goods, the public domain, open research projects, public sector financing of research, or market failures outside of infectious diseases, and they also put brackets around every mention of the need to provide for global mechanisms that would ensure equitable sharing of the costs of essential medical R&D.

Without support from the US, Japan and the EU, there will not be a new global framework – only an increasing emphasis on more and more bilateral and regional trade agreements that raise drug prices.

The high-income countries, particularly the United States, should reconsider their initial negative reaction to this important initiative. For years the United States government has claimed it is looking for new ways of getting its trading partners to share the costs of medical R&D. This is of course the rationale for the many new global trade agreements, such as the US/Australia Free Trade Agreement (FTA), or the many similar agreements recently negotiated with developing countries.

The US has also made several announcements at recent G8 meetings, calling for broader participation in global open source projects to develop new vaccines for AIDS and other public health threats, like SARS or avian influenza. If they reject this effort, it will appear as though they are more interested in getting higher prices for the products US companies sell, than on actually doing something Continuing on page 16 >

> constructive and positive with regard to the sharing of R&D costs. Europe should also reconsider its position on the new global framework. Like the US, Europe is facing a growing crisis of access to the newest medicines for severe illnesses, like cancer. If Europe continues to back only those globalization initiatives to boost drug prices at the expense of access, its own consumers, including in particular the new members of Europe, will face their own access problems.

The Kenya/Brazil proposal, which will be debated in May 2006, should not be seen as a North/South fight, but rather as a positive measure – one that takes a balanced look at the R&D issue, and calls for serious negotiations on the core issues of who will pay for R&D, and what type of R&D do we really need? This can be an example of good globalization. ■

READ ON

WHO Executive Board draft resolution EB117.R13: [Global framework on] essential health research and development
http://www.who.int/gb/ebwha/pdf_files/EB117/B117_R13-en.pdf

The draft text of an experts' proposal for a Medical R&D Treaty
http://www.cptech.org/workingdrafts/rndtreaty.html

A February 2005 experts letter to the EB, proposing evaluation of a Medical R&D Treaty
English http://www.cptech.org/workingdrafts/24feb05WHOen.pdf
Français http://www.cptech.org/workingdrafts/24feb05OMSfr.pdf
Español http://www.cptech.org/workingdrafts/24feb05OMSes.pdf

Open letter from scientists in support of World Health Organisation resolution proposed by Brazil and Kenya
http://www.whoscientistsletter.org/

Neglected Diseases R&D Appeal
http://www.researchappeal.org/

End of page 5 > In fact we did the first needs assessment in collaboration with them, and we are discussing the way forward with them and other partners.

We deal sometimes with NASCOP, sometimes the Divison of Reproductive Health, both under the Ministry of Health, and NAC, the National AIDS Commission, a completely independent body.

> RHN: I understand NASCOP is rather a strong programme, but what about other parts of the bureaucracy? I was just attending a two day meeting of the World Economic Forum here in Nairobi which was demonstrating the weakness of the health systems and bureaucracies in Africa, and trying to galvanise new solutions. You seem to be dealing with quite an active, responsive bureaucracy. Or do you face these problems too?

NK: You do, but you have to willing to negotiate and navigate around them! And perhaps that is one of the challenges of policy-oriented research, because where do you draw the line between engagement with health policy, and actually using research results? To what extent are you an advocate, and to what extent are you a researcher who's getting your research used? It's a very delicate grey area.

> RHN: But you really have to understand the bureaucracy.

NK: Certainly. I think you have to be local, to be honest with you, and have a keen sense of the underlying dynamics and politics.

> RHN: So you become a politician as well...

NK: Gosh! I would never ever see myself as a politician!

> RHN: Changing the activities of government, that's political! But of course you are doing it through evidence... that's a different game.

NK: Certainly it is! **RW** ■

End of page 11 > production within weeks, as it will be produced in cells in the lab, rather than chicken eggs.

But it would be a new vaccine, normally requiring a full series of clinical trials, lasting months or years. But for a world in the midst of a pandemic, that would be too late. So there would be a difficult decision by the US Food and Drug Administration and other such bodies approving pharmaceuticals and vaccines on what tests – if any – should be applied before the vaccine would be approved for use. ■

READ ON

Protection of Mice and Poultry from Lethal H5N1 Avian Influenza Virus through Adenovirus-Based Immunization
Journal of Virology, February 2006, vol 80(4): 1959-64

US Centers for Disease Control - Pandemic influenza
http://www.cdc.gov/flu/pandemic/

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Letters to the editor are also welcome.

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