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THIS WEEK:

A new patriotism for a new South Africa

FOR SOME YEARS NOW we have called for the nurturing of a new patriotism among all our people, both black and white. We have considered this important because for three centuries our people have been separated into antagonistic racial compartments.

And yet these were compartments in one country. Therefore they could only be maintained by force. The longer they were maintained and the greater the force used, the greater the divisions became. The deeper these divisions, the greater became the fears of the white minority of the black majority and the more determined that majority to break out of the compartment into which it had been forced.

This legacy is part of our daily reality. It also informs our thinking about ourselves, about others and about our country. It is out of this legacy that stereotypes of one another were born and are maintained. Some of these stereotypes are indeed most offensive.

As long as these persist, so long will it be difficult for us to achieve the necessary unity across the colour line, focused on a common national

effort to eradicate the unacceptable legacy of the past. Yet, we have to think and act together both because we need to pool all the resources we have as a country and because we must ensure that the new South Africa is a product of the common efforts of all our people.

The only way this will happen is if we proceed from common positions about the nature of the problems our country faces. We must share a common recognition of the fact that all of us stand to gain from the transformation of South Africa into a non-racial, non-sexist and prosperous country.

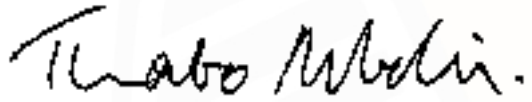
Equally, we need to share a common recognition of the fact that all of us stand to lose from the failure to transform ours into a non-racial, non-sexist and prosperous country. Unless we build such a society, the better life for all that we all seek would be realised neither for the whites nor for the blacks. This means that all of us must engage in a difficult and protracted struggle to defeat the accumulated prejudices that all of us harbour in our minds.

Nobody is born either superior or inferior. No people is predestined to succeed or to fail. No child is born hating. Our neighbours, whether black or white, are as human as we all are and as South African as we all are. Because none of us is an island, none of us can succeed without the co-operation of the next person, regardless of race, colour or gender. Similarly, we cannot build a winning nation and, therefore, winning individuals, unless we combine our efforts to bring about this result.

The new patriotism is therefore a material factor in both our individual and collective efforts to achieve success in our lives. With its adoption, each one of us will find that we become empowered to determine what we can and should do to contribute both to our own advancement and to the attainment of the greater good.

Thus shall we achieve national unity, national reconciliation and the mobilisation of the millions of our people to hold hands as a single mighty movement mobilised to transform ourselves into the winning nation that we can, must and will be.

Joint action to implement the programmes we announced in the State of the Nation Address last Friday provides all of us with the opportunity to give concrete expression to the new patriotism that is in the enlightened self-interest of all of us who call ourselves South African.



HIV/AIDS

Questions that require answers

LAST FRIDAY OUR PRESIDENT presented his annual State of the Nation Address. Even the most consistent critics of the ANC and our Government conceded that this was a high quality address which pointed the way forward for our country.

Nevertheless the opposition parties and their media allies thought it imperative that they find something to criticise. Predictably, they returned to the issue of HIV/AIDS, among others.

This week we have therefore been exposed, once again, to the sterile arguments of this opposition alliance. As before, it has added nothing to the serious debate about AIDS except its tired propaganda. According to this propaganda, all questions about HIV/AIDS were answered a long time ago.

President Mbeki has therefore been called "insane" for asking questions aimed at gaining a correct understanding of this Syndrome, which would enable us to adopt correct strategies to contain the epidemic.

In recent weeks, thoughtful articles on this subject have been published by such serious journals as The *New York Times* (NYT) and *Business Week* (BW).

Since our people in South Africa normally have no access to these publications, we decided to review the articles to which we refer, further to raise the level of understanding and discussion of the important matter of AIDS.

Quite clearly, there are many people in the world who are asking questions about HIV/AIDS. Perhaps they too, like President Mbeki, are "insane".

The *New York Times* article to which we refer is entitled "The AIDS Questions that Linger" and was written by Lawrence K. Altman, M.D. of the NYT. It was published on 30 January.

Early in his article, Dr Altman quotes Sandra Thurman, the top AIDS official in the Clinton administration, saying: "People say that the more we learn about HIV, the more we realise we don't know a whole lot." (Our emphasis).

On the contrary, our own opposition alliance is convinced that it knows everything that needs to be known about HIV. Undoubtedly, it has the answers to the questions posed by Dr Altman, who writes that the list of unanswered questions about HIV/AIDS "could fill a newspaper, and even then would create debate".

Among others, Dr Altman poses the following questions:

- "Why does AIDS predispose infected persons to certain types of cancers and infections and not others?"
- "Equally puzzling is why AIDS patients are also more prone to infections like pneumonia. Studies of the immune system have not answered the question, and 'we do not know very much more about why that is than we did 20 years ago when the first work was done,' said Dr Henry Masur, an official at the National Institutes of Health."
- "What route does HIV take after it enters the body to destroy the immune system?"
- (What) is not known is how the virus proceeds to destroy the body 's CD4 cells that are needed to combat invading infectious agents. 'We need a breakthrough' said Dr David A. Cooper, an AIDS expert in Sydney, Australia."
- "How does HIV subvert the immune system?"
- "(There) is widespread variation in the rate at which HIV-infected people become ill with AIDS. So scientists ask: Can the elements of the immune system responsible for that variability be identified? If so, can they be used to stop progression to AIDS in infected people and possibly prevent infection in the first place?"
- "Anti-HIV drugs suppress replication of the virus, which should give the functioning parts of the immune system a chance to eliminate remaining virus. That does not happen. 'So something is bizarre about that that we don't understand,' Dr Fauci (the director

of the US National Institute of Allergy and Infectious Diseases) said."

- "What is the precise function of HIV genes? HIV's nine genes have multiple functions, but they are only partly known. One gene was called nef (for negative factor) because it was thought to inhibit HIV. But now it turns out to have an opposite effect. Nef accelerates HIV's ability to infect. In the United States, an experimental vaccine made by deleting the nef gene from a simian AIDS virus provided strong evidence of protection against an AIDS-like virus in early tests in monkeys. However, longer-term follow-up showed that the vaccine caused the disease it was designed to prevent."
- "What is the most effective anti-HIV therapy?.What combinations of drugs should be started first and when? Why do side effects like unusual accumulations of fat in the abdomen and neck develop? Is it possible to predict who will get them or how best to treat them?"
- "One avenue being explored is treating for a period of time and then stopping in hopes of stimulating the immune system to combat HIV. An unanswered question is: will it work any better than standard therapy?"
- "Another critical unanswered question is: what is the best way to deliver anti-HIV therapy in the third world where medical facilities are scarce?"
- "Is a vaccine possible. There is little question that an effective vaccine is crucial to controlling the epidemic. But many unanswered questions exist about whether and when one can be developed. When HIV-1 was isolated in 1984, Margaret Heckler, the US secretary of health and human services, promised an AIDS vaccine within a few years. Seventeen years later prospects for an AIDS vaccine still appear quite remote, said Dr Neal Nathanson, the former head of the National Institutes of Health's Office of AIDS Research."
- "It is not known whether a vaccine derived from one type of HIV will confer protection against other types."
- "Scientists also do not yet have some basic information about vaccines against HIV. For instance, they do not yet know which antibodies produced in response to a vaccine indicate the greatest likelihood of protection, a crucial step in developing any vaccine. 'Unfortunately, we still don't have the knowledge to create an effective vaccine, and I honestly don't know if we will ever have one because the problems are so great,' Dr Wainberg, an AIDS researcher at McGill University in Montreal, said."
- "Why do most babies born to infected mothers escape infection?.Why do .75 percent escape? Do these infants manage to mount a successful immune response to avoid infection? Relatively little research has been done to answer these and other questions, said Dr Esparza, the UN official."
- "Why do HIV rates differ so greatly among regions in Africa and elsewhere?.Despite studies, there is no simple explanation for the regional differences, said Dr Piot, the UN AIDS official."
- "Where did AIDS come from? We can only guess. Determining the answer would be important because discovering how AIDS came to be epidemic might prevent a similar catastrophe in the future."

The reader will remember that Dr Altman asked some questions concerning AIDS drug therapy.

In its issue of 5 February 2001, *Business Week* carried an article by John Carey entitled "AIDS Cocktails: Better Later Than Sooner?"

The journal reports that conventional wisdom up to now has been - 'Hit early, hit hard'.

It then reports that:

"(The) Panel on Clinical Practices for Treatment of HIV Infection is about to announce new guidelines that recommend hitting later rather than sooner."

"The guidelines, to be released in early February at a retrovirus conference, will recommend that doctors wait until patients' T-cell counts fall to 350 cells/mm3 before attacking the virus with drug cocktails. 'There was a clear consensus that 500 was too high, and everyone agrees 200 is too low,' explains Dr John G. Bartlett, head of infectious diseases at Johns Hopkins University and panel co-chair. The 350 figure was 'picked as halfway between the two extremes,' he says."

The report continues:

"The reason: It's become starkly clear that the potent medicines have serious limitations. They offer no hope of eradicating the virus. And their side effects - which include heart disease and cancer - are far worse than originally thought."

"'The longer we treat, the more long-term toxicity we see,' says Dr Anthony S. Fauci, co-chair of the treatment panel."

"Adds (Dr) Gordin (head of infectious diseases at the Veterans Administration Medical Center in Washington): 'We've gone from an era when most people were dying from the illness to a time when they are getting complications from the therapy that are almost as bad.'"

"David Barr, director of the Forum for Collaborative HIV Research, calls the change 'dramatic - and very, very important.' "

Both the *New York Times* and *Business Week* are serious publications.

We are certain that the matters they raise will not be dismissed with the same contempt and venom with which the same or similar questions from an African President were met. Furthermore, the scientists quoted by these publications all belong to the 'orthodox' AIDS school. Accordingly, they cannot be dismissed with the ease with which the 'dissidents' have been dismissed.

We are very interested to hear the answers to the questions and issues posed, from our own Minister of Health, and the state institutes of health, such as the Medical Research Council, the National Institute of Virology and the Medicines Control Council.

As our President has insisted all along, this matter is very urgent and concerns the very lives of our people. Let us cite only one instance to explain this urgency.

The Provincial Government of the Western Cape has been trumpeting the fact that it has made AZT available to pregnant women in Khayelitsha. Yet are any cell counts done before the administration of this drug to pregnant African women? At what point in the cell count have these drugs been administered? What measures have been taken to ensure that the women concerned do not develop fatal side effects?

What measures will be taken in the light of the recommendations of the US Panel on Clinical Practices for Treatment of HIV infection? What oversight functions have the Ministry of Health exercised over the actions of the Western Cape, given the well known toxicity of the anti-retroviral drugs, which Drs Fauci and Gordin confirm? Or have the very lives of our people been made hostage to political adventure?

Urgent answers, and not propaganda, are required to all the questions and issues contained in this article.

The *New York Times* quotes Dr Fauci as saying:

"It is the rare person who gets up and strips himself of his personal agenda and articulates what we really do not know because by saying that, they would diminish the impact of their own work, which is their agenda."

Real concern about the health of our people and the millions said to be dying from AIDS throughout our continent, requires that these "rare" people should stand up and be heard. In the interests of life, the truth should no longer be suppressed.

DRUG TRIALS

HIV/AIDS, profit and fundamental human rights

THE STORY OF NONOXYNOL-9, known as N-9, an active ingredient used in chemical barriers to HIV and STD transmission, raises disturbing questions about research ethics, drug company profits and the role in Africa of international development agencies.

Products designed to provide a chemical barrier to HIV and STD transmission, such as N-9, are called microbicides.

According to a circular of the US Centres for Disease Control (CDC), dated 4 August 2000: "From 1996 until May 2000, UNAIDS sponsored a study of the effectiveness of a gel which contained 52.5 milligrams of N-9., compared to an inactive gel. The study was conducted in several locations in Africa. Nearly 1,000 HIV-negative commercial sex workers were enrolled in the trial, and all women were counselled to use condoms consistently and correctly. In addition to condom use, the women were asked to use a vaginal gel each time they had intercourse. Half of the women were provided a placebo (non-active) gel and half of the women received an N-9 gel."

Later, we will report on the results of this trial and the recommendations of the CDC. But before this, we have to give a short account of the history of N-9.

The conclusions of a 1992 N-9 study were published in the journal JAMA 1992 July 22-29; 268(4):477-82 and stated that: "Genital ulcers and vulvitis occurred with increased frequency in nonoxynol 9 sponge users. We (who conducted the trial) were unable to demonstrate that nonoxynol 9 sponge use was effective in reducing the risk of HIV infection among highly exposed women." The trial referred to here was conducted among sex workers in Kenya in 1992.

The results of another study were published in 1993 in the International Journal on STD and AIDS 1993 May-June; 4(3):165-70. This study concluded that: "The rate of epithelial disruption (genital ulcers) for women using N-9 4/day was five times greater than that of placebo users."

After another study conducted in Kenya, the Journal of Infectious Diseases 1991 February; 163(2):233-9, had concluded that genital ulcers were associated with increased risk of HIV-1 infection.

By the time UNAIDS began its studies in 1996, published scientific knowledge was that:

- genital ulcers increased the risk of HIV infection;
- the use of N-9 increased the incidence of genital ulcers; and,

- more frequent use of N-9 led to a higher incidence of genital ulcers.

The August 2000 CDC circular to which we have referred said that the results of the UNAIDS trial were reported at the 2000 Durban International AIDS Conference, as follows:

"At the end of the trial, researchers found that the women who used N-9 gel had become infected with HIV at about a 50% higher rate than women who used the placebo gel. Further, the more frequently women used only N-9 gel (without a condom) to protect themselves, the higher their risk of becoming infected. Simply stated, N-9 did not protect against HIV infection and may have caused more transmission. Women who used N-9 also had more vaginal lesions, which might have facilitated HIV transmission."

As we now know, these precise results of N-9, announced in 2000, were already publicly known by 1993. And yet UNAIDS began its trial in 1996, knowing that N-9 increased the risk of HIV infection, especially among those who might use the microbicide with high frequency, such as prostitutes.

Despite this knowledge, after the results were announced at the Durban AIDS Conference, Dr Joseph Perriens of UNAIDS could still say: "We were dismayed to find out that the group using N-9 gel had a higher rate of HIV infection than the group using a placebo."

South Africa was one of the African countries in which UNAIDS conducted its trial. In a press release issued in Durban on 12 July, 2000, an organisation named AEGiS reported that the sites for the South African trial were Durban and Johannesburg.

It also reported that the Principal Investigators responsible for the trial in these two cities were, respectively, Dr S. Salim Abdool Karim and Dr Helen Rees. At the same time as he was leading investigations into the efficacy of a chemical compound that was known to be extremely harmful, Dr Karim was head of AIDS Research at our Medical Research Council. For her part, Dr Rees was Chairperson of the Medicines Control Council, the body charged with the responsibility of licensing drugs and medicines.

The Business Day edition of 13 July 2000 reported Dr Rees as 'caution(ing) that the (negative) results were not conclusive and more work needed to be done on the issue. She pointed out, for instance, that it was possible that the group using the placebo (or substitute with N-9) may have been exposed to a more active microbicide.' Presumably by saying that "more work needed to be done", she meant that more women needed to be exposed to the highly toxic N-9.

In its edition of August 14, 2000, the Washington Post reported that: "Two U.S.-funded studies involving nonoxynol-9 are underway in African women at risk of HIV. One, sponsored by the Agency for International Development to test the ability of nonoxynol-9 gel to prevent sexually transmitted diseases among a group of women in Cameroon, is due to be completed in September. The other, a study sponsored by the NIAID to look for protection against HIV in women in Zimbabwe and Malawi, is getting underway. In light of the disturbing findings, reported last month at the 13th International AIDS Conference in Durban, South Africa, researchers have abandoned plans to test nonoxynol-9 in that study, said Ward Cates of Family Health International, a non-profit health research organisation that is co-ordinating the project. Cates said there is no evidence that nonoxynol-9 is harmful to women when used as a contraceptive. Nonoxynol-9 is a detergent that is a contraceptive and a microbicide (or germ-killer)."

It is puzzling that Cates should have found it necessary to promote the use of N-9 as a contraceptive, to soften the impact of the negative results announced in Durban.

We do not know whether the US-funded trials in other African countries represent the "more work" to which Dr Rees referred.

The gel mentioned in this article is produced by a US company called Columbia Laboratories Inc and is marketed as Advantage-S. According to the Wall Street Journal, after the N-9 trial results were announced in Durban, Columbia shares 56%, to $5.75. The paper also reported that, nevertheless, President and CEO of the company, Mr William Bologna, said the negative N-9 results "may not be scientifically meaningful."

In a press release dated March 20, 2000, Columbia Laboratories Inc said: "Prospective investors are cautioned that any.(Columbia) forward looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements (of the company). Such risks and uncertainties include, among other things, the successful timely completion of the study now being conducted by the UNAIDS group."

Despite this cautionary note, Columbia Laboratories Inc could not avoid the retribution of either the market or its shareholders. According to the Wall Street Journal, not only did its share price fall dramatically, but it was also sued by its shareholders. The shareholders charged that insiders sold more than $1 million in stock at inflated prices before the results were announced.

This is a highly disturbing story that has directly affected us as a country. It raises a number of questions that require urgent answers, some of which are:

- Why did the MCC approve N-9 trials knowing the toxic effect of this compound?
- Why did Drs Karim and Rees assume the role of principal investigator given the positions they occupied in the state medical institutes?
- What other trials related to HIV/AIDS have been and are being carried out in our country?
- What impact have these trials had on the health of the subjects recruited to participate in these trials?
- Why was the N-9 trial conducted only in African countries (and Thailand) and not the United States, which also has prostitutes?
- What measures have been taken to care for the prostitutes used in the trial, who suffered genital lesions and turned HIV-positive as a result of the use of N-9?
- What measures have been taken to care for other people whose health might have been adversely affected as a result of other trials?
- Why did UNAIDS decide to use our people as disposable objects who could be exposed to N-9, when UNAIDS knew that N-9 had been proved to be toxic?
- What steps has UNAIDS taken to look after the people whose health has been seriously undermined by its wilful activities?
- What will our government do to ensure that this serious matter is attended to?
- Has the attention of the UN Secretary General, the UN Security Council and the General Assembly been drawn to these UNAIDS activities?
- What steps has UNAIDS taken to ensure that especially the developing countries discontinue and do not allow any N-9 trials?
- What role did our Ministry and Department of Health play in the N-9 matter?
- What role have our Ministry and Department of Health played and are playing to ensure that ethical norms are observed in the

conduct of all drug trials in our country, and that the poverty of our people is not exploited to test dangerous drugs here, in a manner that would not be allowed in the developed world?

- Has the informed consent of those who have been involved in the drug trials been obtained and what steps have been taken to ensure that those involved are truly properly informed?
- What measures have been taken to ensure transparency and a system of accountability with regard to the drug trials?
- Once the efficacy and safety of drugs previously tried in South Africa has been established, and these drugs accordingly registered, what steps have been taken to ensure that these drugs are available at affordable prices to our people?

All these questions, bearing on the very lives of our people, require urgent answers.

The story contained in this article speaks of our vulnerability as an African country to the anti-human activities of some corporate forces. It also speaks to our own capacity, as South Africans, willingly to co-operate in the promotion of these activities. It tells a story of how easy it is for some, further to entrench the abuse of already abused African women - this time in the name of science and health.

Dr Rees, Chairperson of the MCC, argues that 'more work' needs to be done on N-9 because the negative results announced in Durban 'were not conclusive'. This sentiment is echoed by the CEO Bologna of Columbia Laboratories Inc., who says that these negative results 'may not be scientifically meaningful.'

On the other hand, the CDC says: "However, given that N-9 has now been proven ineffective against HIV transmission, the possibility of risk, with no benefit, indicates that N-9 should not be recommended as an effective means of HIV prevention."

What we ask is - what else about HIV/AIDS is more about profit and less about the health of our people. Time will tell.