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30 September 2004

THE REGISTRAR: MS PRECIOUS MATSOSO
MEDICINES CONTROL COUNCIL
2nd Floor, Hallmark Building
Cnr Andries and Vermeulen Streets
Pretoria

Dear Ms Matsoso

MCC Review of its Special Registration of Nevirapine for Perinatal Administration, and its Recent Recommendation that Nevirapine be Administered Together with AZT in Perinatal Applications

In view of Council's failure to respond to any of our correspondence in the above two matters, we are proceeding with the preparation of a complaint to the Public Protector, preliminary to taking Council's dereliction of its statutorily mandated responsibilities to the South African public on judicial review, if needs be.

Subsequent to dispatching our last letter to you in the above matter, we located a copy of the finalised version of the draft *Antiretroviral drugs and the prevention of mother-to-child transmission of HIV infection in resource-constrained settings Recommendations for use 2004 Revision* (the 'WHO Recommendations'), which we critiqued in our second, fifth and sixth letters, now entitled *ANTIRETROVIRAL DRUGS FOR TREATING PREGNANT WOMEN AND PREVENTING HIV INFECTION IN INFANTS GUIDELINES ON CARE, TREATMENT AND SUPPORT FOR WOMEN LIVING WITH HIV/AIDS AND THEIR CHILDREN IN RESOURCE-CONSTRAINED SETTINGS* (hereinafter referred to as 'the WHO Guidelines').

The finalised WHO Guidelines are undated, but according to the WHO's website were published on 14 July 2004 – that is, twelve days after Council's meeting at which it decided to disavow nevirapine for solo use to prevent mother to child transmission of HIV in favour of combining it with nucleoside analogue drugs such as AZT.

It is revealed on the 'Acknowledgements' page of the WHO Guidelines that the anonymously produced preceding draft WHO Recommendations were written by long-time collaborators Francois Dabis of the *Institut de Santé Publique, Epidémiologie et Développement (ISPED) Université Victor Segalen Bordeaux 2* in France, and Marie-Louis Newell of the Centre for Paediatric Epidemiology and Biostatistics, Institute of Child Health in London, UK.

Both Dabis and Newell are leading members of the 'IAS Ghent Group' – more fully named 'The Ghent IAS Working Group on HIV in Women and Children'.

'IAS' is the acronym of the International AIDS Society.

The 'Acknowledgements' page of the WHO Guidelines records that a meeting took place 'in Geneva, Switzerland on 5-6 February 2004 convened by the WHO to review the draft recommendations and [make] suggestions on its revision', and that South Africa's James McIntyre attended it.

It is apparent upon a perusal of the finalised WHO Guidelines, however, that there is no substantial difference between their contents and those of the draft WHO Recommendations, and that the former are essentially the latter reframed. It is plain therefore that nothing new or original of any substance was contributed by any of the consultants invited to 'review the draft recommendations and [make] suggestions on its revision', and that Dabis and Newell must accordingly be credited as the principal authors of the finalized WHO Guidelines and of the treatment prescriptions they proffer.

Although winsomely sub-titled *GUIDELINES ON CARE, TREATMENT AND SUPPORT FOR WOMEN LIVING WITH HIV/AIDS AND THEIR CHILDREN IN RESOURCE-CONSTRAINED SETTINGS*, the WHO Guidelines have nothing to say about care and support in the ordinary sense of these expressions and everything to say about what antiretroviral drugs pregnant women and their babies should be put on as soon as possible.

This is because to Dabis and Newell, and AIDS doctors in general, 'care' has acquired the peculiar meaning conceived by the marketing arm of the pharmaceutical industry, namely, the administration of antiretroviral drugs: at a satellite meeting held on 12 July 2004 at the Bangkok AIDS Conference to discuss their about-to-be-released WHO Guidelines, they claimed them to be 'expert consensus documents..developed over the past six months in partnership with the Ghent IAS Group using available evidence and in the context of increasing access to care of women and children'. By this they mean in the context of the WHO's 'Treat 3 million by 2005' with antiretroviral drugs programme, whose motto is emblazoned on the cover of their WHO Guidelines.

This programme dovetails with the long-term marketing strategy of nevirapine manufacturer Boehringer Ingelheim: its summer 2004 edition of *VIRAMUNE-Access Update*, puffed by a front-page colour photograph of a pair of happy natives, explains the company's business development plan:

> Boehringer Ingelheim is in its fifth year since it announced the VIRAMUNE [nevirapine] Donation Programme, one of its contributions to the alleviation of HIV/AIDS around the world. Since then, VIRAMUNE has been provided free of charge for the Prevention of Mother to Child Transmission of HIV. Boehringer Ingelheim and WHO recognise the potential for PMTCT sites to serve as natural entry points for providing access to chronic treatment within the "3X5" strategy. This means that the healthcare infrastructure that has been built up through PMTCT programmes will be leveraged to eventually lead to greater access to chronic treatment in these communities.

Boehringer Ingelheim has even established a caring charity:

> The Boehringer Ingelheim Cares Foundation, Inc. is an independent, not-for-profit tax-exempt organization established in 2001 by the Boehringer Ingelheim Corporation in Ridgefield, CT [Connecticut, US]. The Foundation's mission is to improve lives through innovative philanthropic contributions and donations of healthcare products and resources.

None of the literature concerning the foetal and neonatal toxicity of antiretroviral drugs that was published concurrently with or subsequent to the release of the draft WHO Recommendations on 7 January 2004, which we canvassed in our last letter to Council, was mentioned in the final WHO Guidelines – much less were its grave implications for the use of antiretroviral drugs in pregnancy discussed.

It is evident therefore that neither Dabis nor Newell checked whether any relevant new toxicity research had been reported between the date that their draft WHO Recommendations were released and the publication of the finalised WHO Guidelines more than six months later.

And from their failure to draw these authors' attention to this latest reported research at the Geneva meeting, it is equally plain that none of the people hired to discuss and comment on the draft WHO Recommendations – South Africa's James McIntyre included – had bothered themselves with keeping abreast of the current toxicity literature either.

Dabis and Newell's new WHO Guidelines are accordingly situated solidly within the currently hegemonic chemotherapeutic approach to AIDS, sold to clinicians and academics by the pharmaceutical cartel, a medical paradigm to which the International AIDS Society is entirely beholden – as is plain from the prominent advertisement of the industry's AIDS drugs on the website of the IAS journal *AIDS*, hard copies of which are thick with AIDS drug advertisements.

Although the IAS styles itself altruistically as 'Scientists and Healthcare Workers Committed to HIV/AIDS', in reality what the IAS is 'committed to' is the movement of pharmaceutical industry merchandise. A leading member of Dabis and Newell's IAS Ghent Group, and a prominent consultant on their WHO Guidelines, is Joep

Lange, just-retired president of the IAS, and current chairman of PharmAccess International, an AIDS drug lobby group, whose name unambiguously proclaims its mission in developing countries on behalf of the drug industry cartel.

With the cartel breathing heavily behind them, there's naturally not a mention in the WHO Guidelines of caring in the form of nutritional support for 'children in resource-constrained settings', notwithstanding plenty of reports like Beisel's in October 1996 in the *Journal of Nutrition* (126(10 Suppl):2611S-2615S), **Nutrition in pediatric HIV infection: setting the research agenda Nutrition and immune function: overview**:

> Malnutrition can have adverse, even devastating effects on the antigen-specific arms of the immune system and on generalized host defensive mechanisms. … Immunological dysfunctions associated with malnutrition have been termed Nutritionally Acquired Immune Deficiency Syndromes (NAIDS). Infants and small children are at great risk because they possess only immature, inexperienced immune systems and very small protein reserves. The combination of NAIDS and common childhood infections is the leading cause of human mortality. NAIDS can generally be corrected by appropriate nutritional rehabilitation, but from a viewpoint highly important to this Workshop, AIDS and NAIDS are intensely synergistic. AIDS-induced malnutrition can lead to the secondary development of NAIDS, with its much broader array of additional immunological dysfunctions. The complex and far reaching insults to the immune system caused by NAIDS, and the synergistic combination of NAIDS and AIDS, thereby hasten the demise of many victims of AIDS. Aggressive nutritional support for children with HIV infections could delay, or lessen, the development of NAIDS and avoidance of NAIDS would improve both quality and length of life.

Dabis and Newell's endearing reference in their WHO Guidelines's subtitle to 'women..and their children in resource-contrained settings' is European code for Africans: 'In 2003 an estimated 700 000 children were newly infected with HIV, about 90% of these infections occurred in sub-Saharan Africa.' AIDS drug experiments on pregnant African women and their babies are mentioned throughout the WHO Guidelines. In reference to a clinical trial conducted in Thailand, Dabis and Newell mark the principal intended territory for the application of their WHO Guidelines: 'Although these trial data are reassuring, it is not known whether ZDV from 28 weeks in Africa will result in serious anaemia in programmes where anaemia is common and women are not screened.' And in a recent statement by Newell, discussed below, she urges that 'we cannot ignore the AIDS epidemic taking place today in Africa today' and that 'It is our duty to disseminate the results of this study, and other research taking place across Europe.'

Dabis and Newell's claim that their WHO Guidelines represent the 'expert consensus' springs from the simple expedient of having consulted very narrowly – specifically, only those clinicians known to share their medical thinking.

In the all-important matter of drug safety, Dabis and Newell failed to solicit the advice of any scientist or clinician who has contributed to the foetal toxicity literature. None of the participants in the 'Technical Consultation on Antiretroviral Drugs and the Prevention of Mother-To-Child Transmission of HIV Infection in Resource-

limited Settings' – the meeting mentioned above – 'to review the draft recommendations and for making comments and suggestions on its revision', nor any other persons listed who were approached for 'comment..on [Dabis and Newell's] first draft', nor any of the 'WHO staff [who] contributed to writing these guidelines' have any specific expertise in the subject of toxic pharmacology, both demonstrated in numerous clinical and experimental studies, and potential, having regard to all that is known about the toxicity of AIDS drugs – nucleoside analogues in particular, described by Brinkman et al. in September 1999 in *Lancet* (354 (9184):1112-5) as 'much more toxic than we considered previously'.

On the contrary: another of Dabis and Newell's senior consultants was UNAIDS's HIV/AIDS Programme chief Joseph Perriens (mentioned in our second letter), famously on record in the *New York Times* describing AZT as 'slightly more toxic than an aspirin'. (Like Cape Town University Medical School Dean Professor Nicky Padayachee, a loyal AIDS drug pusher too, Perriens is in the pay of the pharmaceutical drug industry and the American government. Both Perriens and Padayachee are members of another AIDS drug promoting outfit, ECI (Enhancing Care Initiative), 'a multidisciplinary, multinational program that aims to enhance the care of people living with HIV/AIDS in resource scarce countries', co-funded by AIDS drug manufacturer Merck and the US Department of Health and Human Services.)

Another consultant who approved Dabis and Newell's draft was the FDA's thoughtful Ellen Cooper, whom we quoted in our last letter:

> We don't know what the long-term effects of AZT use during pregnancy might be, but so far we have seen virtually no adverse effects in the short term. ... Not one single tumor. Not one. ... I mean [the children] have cancers, lymphomas, and other problems like that..but there's no reason to link those cancers to AZT.

Local consultant James McIntyre is a GlaxoSmithKline asset, who sang AZT's praises ('the *muthi*', he calls it) from the pulpit of the company temple in the centre of the exhibition hall at the 13th International AIDS Conference in Durban in July 2000. Tweedledum to this Tweedledee is his colleague at the Paediatric AIDS Unit at Chris Hani-Baragwanath Hospital, cartel bimbo Glenda Gray, who responded to President Mbeki and Dr Tshabalala-Msimang's stated concerns about the toxicity of AZT in 1999 by pouting in the *Washington Post* on 16 May 2000: 'If they're not going to provide us with AZT then the best thing that the government can do is to ask us to strangle them all at birth.'

This was the luminous quality of the intelligence that Dabis and Newell had at their disposal during the review of their draft WHO Recommendations in Geneva.

Concerning the safety of nevirapine taken during pregnancy, Dabis, Newell and their consultants seem to have short memories. The transplacental cytotoxicity of nevirapine was established in murine studies even before the drug was provisionally licensed in the US in 1996, and thereafter elsewhere in the world, with Boehringer Ingelheim cautioning in its license application to the FDA: 'In rats..a significant decrease in fetal weight occurred at doses producing systemic concentrations approximately 50% higher than human therapeutic exposure.'

Yet the lesson of thalidomide is that humans are much more susceptible to injury by transplacental toxins than animals. In pregnancy safety studies duly conducted by the manufacturer, rodent foetuses experimentally exposed to thalidomide were not born deformed as humans later were (see photograph annexed), which is how and why the directors of thalidomide manufacturer Chemie Grünenthal got off the hook at their prosecution in Aachen, West Germany in the sixties.

And when on 5 January 2001 the US CDC issued a special contraindication advisory against even four-week use of nevirapine by health professionals following needlestick injuries, the Health Systems Trust published a reassuring note a week later in *HealthLink Bulletin* that:

> The South African pilot studies to reduce mother-to-child transmission of HIV through the administration of nevirapine will not be delayed by recent reports of drug toxicity. However the women participating in the program will be closely monitored, according to recent press reports. The CDC in the US recently issued a warning on the toxic side effects of nevirapine when administered *over several weeks*. … These included severe liver damage, when used to treat health care workers accidentally exposed to HIV by needle sticks. However, vertical transmission prevention requires only *one dose* of the drug. … The reports on the toxicity of Nevirapine will have no impact on the Democratic Alliance's proposal to provide the medicine free to HIV-positive pregnant women in the party's controlled municipalities. Party spokesman Sandy Kalyan said reports of Nevirapine being potentially harmful concerned *multiple doses* of the drug. …The South African Medicines Control Council last year registered nevirapine and approved its use for trials after UNAIDS and WHO endorsed the drug as a safe treatment for *one-off use* in the recommended dosage, saying the benefits outweighed the potential adverse effects. [*Our emphasis*.]

In embracing Dabis and Newell's WHO Guidelines, Council has abandoned its former caution, having regard to the CDC's warning three years ago that 'healthy persons taking abbreviated 4-week NVP regimens for PEP are at risk for serious adverse events' such as 'Severe, life-threatening, and fatal cases of hepatotoxicity and skin reactions. … The median onset of these symptoms was 14 days after beginning NVP for PEP (range: 3 – 36 days).'

Irrespective of this, the WHO Guidelines propose that African women endure the acute, severe toxicity of nevirapine throughout their pregnancies, with their unborn babies exposed transplacentally all the while, no matter that rodent studies conducted by Boehringer Ingelheim found 'significant decrease in fetal weight' resulting from exposure in utero.

Even single-dose nevirapine treatment after birth has again been shown recently to be very toxic for a high proportion of treated babies: a study by Taha et al., **Nevirapine and zidovudine at birth to reduce perinatal transmission of HIV in an African setting: a randomized controlled trial**, was published in *Journal of the American Medical Association* (292(2):202-9) on the same day as the WHO Guidelines – which mentioned the study (citation 33) as a paper still in press that 'showed no benefit of adding ZDV for one week to neonatal single-dose NVP when the mother had received intrapartum NVP'.

What Dabis and Newell neglected to mention in their WHO Guidelines is that the study also found an incidence of 'Grades 3 and 4 adverse events' at a rate of '4.9%..and 5.4%..in infants receiving NVP only and NVP plus ZDV, respectively'. That is, one in twenty African babies suffered serious toxic reactions to the drugs. But then the AIDS doctors who reported the study weren't troubled by this either, noting simply: 'The safety of the regimen containing neonatal ZDV was similar to that of a standard NVP regimen.'

Dabis and Newell's failure to consult broadly goes some way to explaining why they gave the 'available evidence' concerning the foetal toxicity of antiretroviral drugs such short shrift in their draft WHO Recommendations and finalised WHO Guidelines.

A further reason accounting for the dangerously inadequate two-page treatment they accorded the all important issue of maternal, foetal and neonatal safety in their fifty page WHO Guidelines is the fact that both of them are epidemiologists, an medical speciality concerned with tracking the occurrence of disease in given populations – a distant remove from clinical medicine, molecular biology, molecular pharmacology, medical toxicology and pathology. (This also explains their shared ignorance and their fundamental misapprehensions as to the (very limited, *non-diagnostic*) clinical meanings of antibody and genetic 'HIV' test results, on the fallacious basis of which they have erected their careers in purportedly preventing African mothers from infecting their babies with HIV.)

In writing their WHO Guidelines, notwithstanding their professional interest in disease incidence, neither Dabis nor Newell had any regard to the appearance of *clinical* disease among the babies in the studies they cited; instead their preoccupation was with laboratory testing outcomes, on the corrupt assumptions that HIV-antibody-positive, or a certain 'viral load' measure, equates with disease (HIV-infected), and the inexorable development of disease (AIDS). Which is flat wrong on all scores. We've dealt with the tests before; in March 2002 Morgan et al. reported in *AIDS* (16:597-603) that untreated 'HIV infected' Ugandans are surviving 'considerably longer than has been expected'. Just as all the predictions once made for supposedly deadly Hepatitis C Virus have likewise flopped.

Like all AIDS doctors propounding the use of the pharmaceutical industry's wares in pregnancy, Dabis, Newell and their consultants also appear to be unaware of the European Collaborative Study's finding reported in *Lancet* in November 1988 (2(8619):1039-43) that without any drug intervention most babies spontaneously sero-revert to HIV-negative in any event. Which is to say – proceeding from AIDS doctors' universal fallacy that HIV-positive means HIV-infected – that most HIV-positive babies spontaneously cure themselves of HIV infection without the intervention of AIDS doctors and their pills.

And as we pointed out in our last letter, several studies in which the clinical effect of treating pregnant women with AZT has been investigated have found that babies exposed to the drug in utero suffer substantially higher death, serious disease and other health impairments than unexposed babies. And the HIVNET 012 single dose nevirapine regimen has been found to have no clinical health benefit when the mortality rate of treated children is compared with that of untreated ones.

Despite the fact that the HIVNET 012 study was a hopeless mess (and for some remarkable news, see the post script hereto), Dabis and Newell persist in citing it in their WHO Guidelines in support of the single-dose perinatal nevirapine regimen tried in the study (citations 7 and 8).

Boehringer Ingelheim's main German website also still pretends that nothing's remiss:

> Viramune® may be used alone as a single oral dose to the mother during labour and a single oral dose to the infant within 24 hours after birth for the prevention of mother-to-child transmission of HIV-1 pregnant women who are not taking antiretroviral therapy at time of labour.

But the company hastens immediately thereafter to make clear that this special drug indication is intended for dun-hued mothers and babies, not fair ones:

> Disclaimer:
> We recognise that the Internet serves a global community. The pharmaceutical industry, however, is subject to country specific regulatory considerations, which affect the information we can provide on our products. In addition the registration status of pharmaceutical products may not be the same in different regions of the world and the approved product labels may also differ according to country specific requirements.
> Therefore please check the registration details of this/these product(s) locally in order to get up-to-date information.
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Ignorant of the toxic pharmacology of antiretroviral drugs at a molecular level, epidemiologists Dabis and Newell reassure us about the safety of the drugs they indicate by citing some favourably low adverse event reporting data – failing to appreciate, as Null et al. note in their comprehensive review of contemporary iatrogenesis in the US, **Death by Medicine**, published online in December 2003, that 'As few as 5% and only up to 20% of iatrogenic acts are ever reported' – in support of which observation the researchers cite several authoritative investigations, to wit, by Leape LL. **Error in medicine**. *JAMA*. 1994 Dec 21;272(23):1851-7; Vincent C, Stanhope N, Crowley-Murphy M. **Reasons for not reporting adverse incidents: an empirical study**. *J Eval Clin Pract*. 1999 Feb;5(1):13-21; Wald, H and Shojania, K. **Incident Reporting in Making Health Care Safer: A Critical Analysis of Patient Safety Practices**, Agency for Healthcare Research and Quality (AHRQ), 2001; Dickinson JG. **Dickinson's FDA Review**. March 2000; 7 (3):13-14; and Cohen JS. *Overdose: The Case Against the Drug Companies*. 2001, Tarcher-Putnum, New York.

The case of thalidomide neuropathy is also instructive concerning the limits to safety conclusions that can be drawn from toxic injury reports. Although well-known as a foetal teratogen, little known is that thalidomide is a potent neurotoxin, which caused many thousands of adult Europeans ingesting the drug to suffer permanent neuropathy at an incidence of about one in five exposures. Yet not a single report of neuropathy among lepers given the drug in the developing world has been published in the medical literature.

The perfect harmony between the commercial aims of the pharmaceutical drug industry, those of Dabis and Newell's IAS, and those of the WHO, are naturally and inevitably manifest in the WHO Guidelines.

Dabis's professional commitment to the administration of synthetic pharmaceutical drugs as the perfect solution to what he declaims dramatically in the preface to the WHO Guidelines as 'the greatest health crisis the world faces today', to the exclusion of all alternative nutritional and natural treatment modalities, is evident from his discouragement of breastfeeding by HIV-positive mothers in his WHO Guidelines and from other platforms, and his bid (in *Lancet* 1998 Aug 22;352(9128):653-5) to discredit research published by the Harvard School of Public Health that has shown that vitamin supplementation is effective in reducing mother to child transmission of HIV according to the usual surrogate indices.

Dabis and Newell's professional bias in favour of the use of antiretroviral drugs during pregnancy and after birth, the blithe manner in which they discount the toxicity literature, where they treat it at all, and their disregard of alternative non-toxic interventions, arise from the following:

Both have long championed the administration of AZT to pregnant women in the developing world, and cite their own research work, its interpretation and the conclusions they draw from it, in support of the recommendations they make in the WHO Guidelines. Indeed, an ardent proponent of AZT use in pregnancy, on which he has built his career and reputation, Dabis cites his own experiments on African mothers and their children in Côte d'Ivoire and Burkina Faso in support of his antiretroviral drug treatment recommendations expressed in the WHO Guidelines no less than five times – citations 11, 16, 23, 24, 38 – more than any other researcher's.

Dabis's manifest conflict of interest arising from his own professional investment in the administration of AZT to Africans naturally disqualifies him from (a) giving impartial consideration to 'the available evidence' where it militates against the medical treatment he has made his name advocating, i.e., the latest research reports concerning the harm it causes children, (b) from according these findings due weight, and (c) from considering the possibility that the relatively recent (only decade-old) medical practice of exposing mostly non-white unborn and newly born babies to such potent transplacental cytotoxins as AZT, 3TC and nevirapine has been a grave mistake, a terrible wrong turn in contemporary medical practice.

Newell's professional incompetence in assessing the significance of the latest published evidence that AZT and 3TC have seriously harmful toxicity for unborn and newly born babies, and consequently should never be used during pregnancy and post partum, is revealed by the fact that two months after the French Paediatric HIV Infection Study Group published its final report in August last (the Barret study referred to in our second, fifth and sixth letters) concerning the serious, sometimes fatal, foetal and neonatal toxic effects of AZT or AZT+3TC, she wrote (with Thorne) in **Antenatal and neonatal antiretroviral therapy in HIV-infected women and their infants: a review of safety issues**, published in the October-December issue of the Polish paediatrics journal *Medycyna wieku rozwojowego* (7(4 Pt 1):425-36), that

> Concerns regarding mitochondrial dysfunction in children with foetal/neonatal exposure to zidovudine have arisen following a report from France of eight

> uninfected children with mitochondrial dysfunction, of whom two died. However, there is limited additional evidence of clinically evident mitochondrial disease in children exposed to antiretroviral therapy in utero or neonatally, and the absence of any excess mortality in large observational cohort studies of children born to HIV infected women and exposed to antiretroviral drugs is reassuring.

Newell's reference was to what the French Paediatric HIV Infection Study Group called their 'Preliminary report' (the Blanche report) four years earlier. She'd apparently missed its final one (the Barret study) in August.

That only a few children were reported killed by AZT and 3TC in the 'Preliminary report' Newell considered 'reassuring'. That other children were reported gravely neurologically crippled, she evidently thought to be of no account. And passing her by was the obviously defective methodology in other studies that counted drug deaths only and thereby missed further such grave injury cases – as discussed in the Barret study. Even less did it enter Newell's head that very many more cases of subclinical neurological harm would have gone unrecorded in 'observational cohort studies' as coarse as corpse counts.

In this latter regard, we wish to emphasize that it is not only gross and sometimes fatal neurological damage caused by the use of antiretroviral drugs in pregnancy that ought to be of concern to Council, but also subclinical irreversible neurological injury – the sort of damage that would not be immediately apparent upon clinical examination and so would not attract closer attention and investigation, as was the case in the drug-exposed children investigated by French Paediatric HIV Infection Study Group (the Blanche alert, the Barret study), where electrophysiological investigation of every drug-exposed child, including the recording of sensory nerve action potentials (SNAPs), would doubtlessly have detected wide-scale subclinical neuropathy. The French Group researchers' failure to appreciate this would certainly have led to countless damaged children going unrecorded, since the only children investigated were those who exhibited gross clinical manifestations of drug injury.

Of all human organs, the brain and nervous system is the most sensitive to toxic chemical damage, especially during foetal and neonatal development. Significant permanent chemical harm to the nervous system may go undetected without specialised testing, and yet will substantially diminish a child's and later adult's quality of life.

It's revealing that in common with Dabis and all other AIDS doctors, Newell also disdains natural childbirth and breastfeeding by African women diagnosed HIV-positive in favour of surgeons' knives and formula milk. This is despite the absence of any clinical evidence whatsoever that African babies delivered by medically imposed Caesarean section have better clinical health outcomes than babies born naturally. And, as might be expected by any informed person with any common sense, there is equally no clinical evidence whatsoever that babies denied their mothers' breast milk at the instance of AIDS doctors are healthier than babies fed factory-produced formula milk – whatever the mothers' 'HIV status'. But the abstract to Newell's article in *Med Wieku Rozwoj* nonetheless commenced brightly:

> Specific interventions to prevent mother-to-child transmission (MTCT) include antiretroviral therapy, elective caesarean section and avoidance of breastfeeding. Rates of MTCT below 1-2% are now achievable in developed country settings.

A recent press release by her University College, London – on 14 September 2004 – quoted Newell making the same claim:

> HIV infected pregnant women who choose an elective caesarean can reduce by half the risk of infection to their child, while breastfeeding increases the risk of transmission. Although with the application of a number of interventions, the rate of mother-to-child infection has been successfully reduced to 1% in Europe, we cannot ignore the AIDS epidemic taking place today in Africa today. It is our duty to disseminate the results of this study, and other research taking place across Europe.

Ghent IAS Group member Ruth Nduati expressed this perverted medical antipathy – standard among AIDS doctors, yet contrary to reams of literature reporting the benefits of breastfeeding for every aspect of physical and intellectual development and long term health, and the harmful deficiencies of substitute factory-made milk – in her opening address at an IAS meeting on 16 July 2003 to discuss and promote the use of AIDS drugs during pregnancy, in which she alleged that 'breastfeeding continues to diminish the efficacy of protocols to administer' AIDS drugs to pregnant women, because, she said, 'about 44% of the transmission is through breastfeeding'.

(This orthodox medical stupidity is currently being imparted by South African AIDS doctors to African women at antenatal clinics and hospitals: David Coetzee told the IAS meeting that '96 per cent of the women [attending antenatal clinics in the poor shack settlement of Khayelitsha, Cape Town] said they did not breastfeed at all..in order to prevent transmission to their child'.)

Clearly ignorant of the latest published toxicity research canvassed in our sixth letter, and dull to the dire significance of the toxicity reports that she glossed over in her WHO Guidelines, Newell again (in this latter document) shared with us that she found it 'reassuring' that

> MTCT prophylaxis with short-course ZDV was not associated with short-term clinical or laboratory toxicity among pregnant women in several controlled trials and long-term follow-up. Trials from Thailand suggest that serious anaemia in women receiving ZDV from 28 weeks of pregnancy is rare and no increase in serious haematological toxicity was observed with ZDV started at 36 weeks in trials in Africa. Although these trial data are reassuring, it is not known whether ZDV from 28 weeks in Africa will result in serious anaemia in programmes where anaemia is common and women are not screened.

In other words, although it's 'not known whether ZDV from 28 weeks in Africa will result in serious anaemia' – that is, potentially fatal destruction of infant (and maternal) bone marrow and red blood cells – Dabis and Newell suggest that the drug be prescribed to African women throughout their pregnancies regardless:

> Although there are concerns relating to potential effects of ARV drugs on the developing fetus, suspending treatment during the first trimester is generally not recommended. … For eligible women, ARV treatment should be started as soon as possible during pregnancy. … ZDV [AZT] should be included in the regimen whenever possible. … A regimen consisting of ZDV starting from week 28 of pregnancy, single dose NVP and ZDV during labour plus ZDV for one week given to the infant is highly efficacious.

It's worth mentioning, as a vignette showcasing the quality of thinking expressed in their WHO Guidelines, that Dabis and Newell cite Bardeguez et al. (in *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, 2003, 32(2): 170–181) noting that 'HIV-related disease progression does not appear to be altered by receiving ZDV prophylaxis'. That is to say, taking antiretroviral drugs does not make sick pregnant women better, or prevent healthy pregnant women getting sick on the drugs – a finding they elsewhere contradict in their WHO Guidelines: 'Potent combination treatment has substantial benefits for the woman's health..'

This latter claim – right out of a drug industry advertisement – is contradicted by numerous clinical studies, most recently by Reisler et al. in *Journal of Acquired Immune Deficiency Syndromes* (2003 Dec 1;34(4):379-86); and by Brown et al., who presented similar, albeit obfuscated findings at the 15th International AIDS Conference in July 2004 in Bangkok: **Non-AIDS serious adverse events are as important as AIDS events in patients with advanced multi-drug resistant HIV disease**.

Upon an analysis of 'serious or life-threatening events that are not AIDS defining, AIDS events, and death among patients treated with highly active antiretroviral therapy (HAART) in the setting of 5 large multicenter randomized treatment trials conducted in the United States' Reisler et al. discovered, as they reported both in their conclusion and in the title to their paper, that **Grade 4 events are as important as AIDS events in the era of HAART**, i.e. that people given 'potent combination therapy' have an approximately equal chance of being dangerously poisoned or killed by AIDS drugs as they do of developing AIDS defining diseases. Which, in as many words, GlaxoSmithKline long ago admitted that AIDS drugs can cause in its entry under 'Retrovir' (AZT) in the *Physician's Desk Reference*: '..it was often difficult to distinguish adverse events possibly associated with administration of Retrovir from underlying signs of HIV disease or intercurrent illnesses.' And all of which would lead most ordinary guys to wonder what the point of taking the drugs is, in pregnancy especially.

By their silence as to the critical matter of drug dosing levels, Dabis and Newell imply in their WHO Guidelines that the prophylactic doses of AZT, 3TC and nevirapine combinations given to pregnant African women and their newborn babies should be the same as therapeutic ones – the ones good at causing life-threatening Grade 4 events.

This reading is supported by the US Department of Health and Human Services's publication *A Guide to the Clinical Care of Women with HIV* (2000), which echoes the US CDC's still current recommendation in *Morbidity and Mortality Weekly Report* 1998; 47[RR-2] that 'pregnant women should be treated according to standard

guidelines for antiretroviral therapy in adults'. In other words, American AIDS doctors don't see any need to reduce the usual dose to protect the foetus.

These dose recommendations, however, were made during the 'hit early, hit hard' HIV treatment era in full swing, with high-dose, multi-drug combinations being the medical convention, before the reported human toll on AIDS patients – described by AIDS treatment expert Professor Michael Saag of the University of Alabama in *Esquire* on 1 March 1999: 'They aren't dying of a traditionally defined AIDS illness. I don't know what they're dying of, but they are dying. They're just wasting and dying.' – led the US Department of Health and Human Services to renounce this brutal mediaeval treatment orthodoxy in favour of delaying initiation of antiretroviral treatment for as long as possible:

On 5 February 2001 the US National Institutes of Health released their *HIV Treatment Guidelines Updated for Adults and Adolescents* – summed up by US government's top AIDS don, National Institute of Allergy and Infectious Diseases (NIAID) director Anthony Fauci the day before in the *New York Times*: 'We are adopting a significantly more conservative recommendation profile' – the idea being, as the reporter paraphrased him, to allow 'the virus to remain in the body longer in return for sparing the patient the drug toxicities'.

This official U-turn in AIDS treatment policy, abruptly and somewhat embarrassingly ending AIDS doctors' 'hit early, hit hard' craze, was followed by another officially endorsed reversal: patients put on antiretroviral drugs should be given treatment holidays to 'reduce toxicity':

Short-cycle structured intermittent treatment of chronic HIV infection with highly active antiretroviral therapy: effects on virologic, immunologic, and toxicity parameters by Dybul et al. – including Fauci – was published in December the same year in *Proceedings of the National Academy of Sciences* (98(26):15161-6), reporting that by all conventional surrogate markers patients did no worse from having treatment holidays: a week on, a week off. This paper thus debunked the 'resistance' argument with which AIDS doctors had terrorised their suffering patients to 'adhere' to their drug prescriptions or die.

Since 'Adherence to such a regimen may be problematic for certain patients', i.e. even alternate weeks will be unendurable, the same principal authors (Fauci included again) have recently came up with another idea: **A proof-of-concept study of short-cycle intermittent antiretroviral therapy with a once-daily regimen of didanosine, lamivudine, and efavirenz for the treatment of chronic HIV infection**, published in June this year in the *Journal of Infectious Diseases* (189(11):1974-82), found that it did no harm to reduce drug combination intake to one dose a day.

But paying no heed to these huge, successive retreats from formerly aggressive AIDS treatment convention, Dabis and Newell's WHO Guidelines offer no such medical mercy for pregnant African women and their babies, and instead move in precisely the opposite direction. Whereas in 1998 UNAIDS, the WHO and UNICEF endorsed short-course AZT treatment of pregnant women to reduce mother to child transmission of HIV, Dabis and Newell's current WHO Guidelines urge aggressive

triple combinations of AZT, 3TC and nevirapine, administered without respite throughout pregnancy or started after a month into it.

The look of it is that as AIDS drugs are being progressively retired in the north, with the mounting toxicity data threatening to block out the sun (as was the case with mercury and arsenic salts in their dying days in the early 20th century), the pharmaceutical industry is manoeuvring to dump them in the south.

This is what happened after the thalidomide disaster: in 1965, as German prosecutors were preparing the indictment of Chemie Grünenthal's directors for their criminal prosecution, the company resumed production of the drug to take up the slack in its vast production capacity. Since thalidomide had been invented as a cell-poison in 1953, and had initially been marketed for a couple of years from 1956 onward as an antibiotic for respiratory infections (it was notoriously repackaged as mother's little helper between 1958 and 1962), Chemie Grünenthal began marketing the drug in the third world as a treatment for out-of-sight lepers. The 'inevitable result', according to the *Oxford Companion to Medicine* is that '''thalidomide babies" are once again being born', notably all over South America.

Incredibly, in 1998 the WHO approved this new treatment indication. Four years later the WHO quietly revoked its imprimatur on this diabolical abuse, but without any concessions as to the harm it had caused and the magnitude of the organisation's failure to the most vulnerable of the developing world's poor. Thalidomide continues to be manufactured and hawked in South America, where it is still deforming children on that continent today. (Could it be that the absence of any public outrage over this in the West is due to the fact that the deformed children are not white?)

The WHO's support, until recently, for the use of thalidomide in the developing world, right after it had been banned in the first, presents a vivid illustration of how the WHO has been hijacked by the pharmaceutical cartel and by the faithful clergy it directly and indirectly retains in medical orders worldwide; and it explodes any illusion that the WHO functions an impartial international body applying the best available science, and beyond the dictates of the cartel's utterly ruthless commercial programme.

We suggest that the integrity, authority and reliability of the WHO Guidelines should be assessed in the light of the organisation's colossal betrayal of the people of the developing world in the recent thalidomide fiasco.

Dabis and Newell make their violent treatment proposals despite a mass of foetal toxicity and multi-drug toxic synergy reports that have been published subsequent to the adoption of the AZT short-course policy in 1998.

Any informed and thoughtful doctor would have been impelled to greater caution by these studies, but instead, for unborn (and newly born) African babies, Dabis and Newell recklessly extend the duration and variety of drug exposure. And without thinking, Council goes along.

The WHO Guidelines effectively codify best clinical practice regarding the prescription of AIDS drugs to HIV-positive women and their babies in the developing

world; and after the brief single-dose nevirapine interregnum, they mark the return of AZT with a vengeance.

Having been synthesized as an experimental cell poison in 1961 (see the writer's essay *Inventing* AZT posted at www.tig.org.za), AZT was licensed by the FDA in 1987 as an AIDS drug not because it had any demonstrated antiviral activity (it was pertinently noted by the FDA licensing panel that none had been shown – and still hasn't, as you will have read in Papadopulos-Eleopulos's et al. mammoth analysis of the molecular pharmacology of the drug that we sent up to you), but because it appeared, on a superficial look at the mortality data in the Phase II AZT trial, to extend lives (but see the writer's exposé of the trial, *Licensing* AZT, on the said website).

AZT and 3TC are nucleoside analogues, a class of drug employed in cancer chemotherapy purposely to kill human cells, as discussed in a leading textbook in this subject by Cheson et al, *Nucleoside Analogs in Cancer Therapy* (Marcel Dekker Inc. New York, 1997).

And don't go believing GlaxoSmithKline's lies that AZT is somehow specific for HIV and doesn't kill human cells like all other nucleoside analogue drugs in its chemical class ('Competition by zidovudine-TP for HIV reverse transcriptase is approximately 100-fold greater than for cellular DNA polymerase alpha'), because Gill et al. reported great success slaughtering blood cells with AZT in a study reported in June 1995 in the *New England Journal of Medicine* (332(26):1744-8): **Treatment of adult T-cell leukaemia-lymphoma with a combination of interferon alfa and zidovudine**. As did Ermine et al. simultaneously in the same journal: **Treatment of Adult T-Cell Leukemia-Lymphoma with Zidovudine and Interferon Alfa**.

Other researchers too: Matutes et al. published effective results using **Interferon alpha and zidovudine therapy in adult T-cell leukaemia lymphoma: response and outcome in 15 patients** in the *British Journal of Haematology* in June 2001(113(3):779-84).

For killing blood cells, AZT's as good as ever: Aouba et al. have recently published a study consistent with those preceding: **Hemophagocytic syndrome as a presenting sign of transformation of smoldering to acute adult T-cell leukemia/lymphoma: efficacy of anti-retroviral and interferon therapy** in June 2004 in the *American Journal of Hematology* (76(2):187-9). But then the bottle – labelled by Sigma Chemical Company more honestly than GlaxoSmithKline – does say: '**Toxic** Toxic to inhalation, in contact with skin and if swallowed. Target organs: Blood Bone marrow … Wear suitable protective clothing.'

AZT's not only deadly poisonous to blood cells; it's been used with great effect to deliberately kill other human tissues too: in January 1999, in the *Journal of the American Academy of Dermatology* (40(1):116-21), Chan et al. reported **A novel chemotherapeutic regimen (interferon alfa, zidovudine, and etretinate) for adult T-cell lymphoma resulting in rapid tumor destruction**.

The dangers of exposing a growing foetus to nucleoside analogues are accordingly well-recognised in cancer chemotherapy.

Citing, inter alia, *The Chemotherapy Source Book* (3rd edition). Ed. Perry, Lippincott Williams and Wilkins, 2001; *Martindale: the complete drug reference* (33rd edition). Eds. Sweetman et al. Pharmaceutical Press, 2002; and the *British National Formulary* (46th edition). British Medical Association and Royal Pharmaceutical Society of Great Britain, September 2003, CancerBACUP, 'Europe's leading cancer information service' warns:

> It is not advisable to become pregnant or father a child while taking fludarabine [a nucleoside analogue drug] as it may harm the developing foetus. It is important to use effective contraception whilst taking this drug, and for at least a few months afterwards.

Another cancer treatment information service, CancerHelp UK, warns alike concerning the use of the drug. Because it

> stop[s] cells making and repairing DNA …This drug may have a harmful effect on a baby that is developing in your womb. It is not advisable to become pregnant or father a child if you are having this drug. You should talk about contraception with your doctor before having the treatment.

The American Cancer Society similarly warns under 'Pregnancy':

> Although pregnancy may be possible during chemotherapy, it is not advisable because some chemotherapy may cause birth defects. Doctors advise women of childbearing age, from the teens through the end of menopause, to use birth control throughout their treatment.
>
> - If a woman is pregnant when her cancer is discovered, it may be possible to delay chemotherapy until after the baby is born.
>
> - For a woman who needs treatment sooner, the doctor may suggest starting chemotherapy after the 12th week of pregnancy when the fetus is beyond the stage of greatest risk.
>
> - In some cases, termination of the pregnancy may be considered.
>
> If you or your partner is considering pregnancy after completing chemotherapy, discuss the matter with your physician.

But for unborn African babies, AIDS doctors such as Dabis and Newell propose that a lesser safety standard be applied than for white ones in the first world, throwing to the wind the well-settled medical convention that growing human foetuses should not be exposed to cytotoxic nucleoside analogue drugs generally, and not during the first term in particular – especially since chemotherapeutic drugs in pregnancy have been shown in animal studies to cause cancer in offspring: in the case of AZT specifically, in the studies we surveyed in our last letter, and chemotherapeutic drugs generally, as Llombart found way back in September 1976, reporting in *Das Osterreichische Kneipp-Magazin* (3(3):72-7) **Tumoral drugs as possible blastogenic agents: the problem of anti-blastic medication**.

Llombart made ‘careful note..of the possible appearance of tumors throughout the lives’ of 1264 rats born to mothers treated with double the usual kg/day human dose of a range of standard chemotherapy drugs. In an incidence of tumour development of up to 37.42 % following transplacental foetal drug exposure, ‘The benign forms predominated in all the tumors produced, but with some of the drugs the malignant varieties produced were made as 39.3% of the tumors. The location and type of tumors were variable; there being cutaneous, glandular, mammary, hepatic, renal, and tumors of the nervous system; there were also tumors of epithelial, connective and nervous variety.’

That chemotherapeutic drugs similar to AZT and 3TC cause permanent *late-onset* brain and neurological damage even among adults with fully formed brains and nervous systems has been reported in a string of recent papers.

Van Dam et al. began by reporting **Impairment of cognitive function in women receiving adjuvant treatment for high-risk breast cancer: high-dose versus standard-dose chemotherapy** in February 1998 in the *Journal of the National Cancer Institute* (90(3):182-3). Their paper in *Cancer* a year later, **Cognitive deficits after postoperative adjuvant chemotherapy for breast carcinoma** (90(3):182-3), reported the ‘late effects on neuropsychologic functioning of CMF adjuvant chemotherapy’ years after cessation of treatment, and found objective evidence of

> Impairment in cognitive function..in 28% of the patients treated with chemotherapy compared with 12% of the patients in the control group … Cognitive impairment following chemotherapy was noticed in a broad domain of functioning, including attention, mental flexibility, speed of information processing, visual memory, and motor function.

Other confirmatory studies have followed, most recently by Wefel et al. in June this year in *Cancer* (100(11):2292-9). The title of their report augurs grimly: **The cognitive sequelae of standard-dose adjuvant chemotherapy in women with breast carcinoma: results of a prospective, randomized, longitudinal trial.**

All these findings are consistent with those of the French Paediatric AIDS Study Group, which reported crippling, sometimes fatal, neurological injuries to babies exposed to AZT and 3TC in utero and post partum – findings to be expected in the light of Busidan’s et al. report in the *Journal of Pharmacological Science* in December 2001 (90(12):1964-71) concerning **AZT distribution in the fetal and postnatal rat central nervous system**:

> The distribution of 3'-azido-3'-deoxythymidine (AZT, zidovudine), an antiviral drug used in the treatment of human immunodeficiency virus, was investigated in gestation day-20 (G-20) fetuses and in postnatal day-20 (PND-20) rats. At both ages, a single dose of 150 mg/kg (1.78 mmol/kg) AZT was administered orally along with tracer amounts of 14C-AZT, and rats were randomly killed at 15, 30, 60, 120, or 240 min after dosing. The fetuses, brains, and spinal cords were processed for autoradiography. … In the G-20 rats, the brain showed higher levels of AZT than spinal cord only at the 30-min sample time, whereas in the PND-20 rats, greater radioactivity was found in the spinal cord up to the 240-min sample time. This pattern of AZT distribution in the central nervous system may hypothetically be attributed to

> the postnatal development of an organic anion carrier system believed to be responsible for transporting AZT from the brain to the blood, resulting in relatively greater overall exposure of the spinal cord to AZT than observed in the brain.

It's really no coincidence that the CDC should have added 'AIDS dementia' to its list of AIDS defining illnesses in the same year, 1987, that AZT was licensed in the US as an AIDS drug, in the light of Bacellar's et al. report in the October 1994 issue of *Neurology* (44(10):1892-900) that

> the risk of developing HIV dementia among those reporting any antiretroviral use (AZT, ddI, ddC, or d4T) was 97% higher than among those not using this antiretroviral therapy. … In addition, the findings of our analysis seem to confirm previous observation of a neurotoxic effect of antiretroviral agents..linked..to the development of toxic sensory neuropathies, usually in a dose-response fashion.

The neurological injury of children reported by the French Paediatric HIV Infection Study Group in 1999 and 2003 was consistent with this finding.

Relying blindly on the incompetents responsible for producing the WHO Guidelines, Council's recent recommendation that HIV-positive pregnant women be given AZT has put thousands of South Africans, mostly black, mostly poor, at risk of suffering the same iatrogenic tragedy.

Council's demonstrated fealty to the pharmaceutical cartel at the expense of the welfare of our South African people, mostly black, mostly poor, underscores the urgent need for a radical overhaul of its composition. In this regard, we think an observation made by KwaZulu-Natal Health MEC Dr Zweli Mkhize a few years ago rather apposite: 'There is in this country a long history of whites telling us what do with our bodies … There has always been this debate about Africans determining what is right for Africans, not whites.'

It's a curious coincidence that the IAS Ghent Group's caring mission into Africa on behalf of GlaxoSmithKline and Boehringer Ingelheim should sue out from Belgium – as does *Médecins Sans Frontières* on the same drug-dealing trip. Of all Europe's colonial projects in nineteenth and twentieth century Africa, Belgium's Congo was the most callously murderous, killing, according to the best scholarly estimates, about ten million Africans.

As he raped the country, Leopold II (honorary president of the British Aborigines Protection Society) sold his depredations to the believing world as a Christian crusade to secure the 'abolition of the traffic in slaves', an involvement motivated by 'the noble aim of rendering lasting and disinterested services to the cause of progress'.

Some might see the same criminal energy pumping behind it, the same metaphysical corruption driving it. We do. *Plus ça change, plus c'est la meme chose.* The horror, the horror.

Yours faithfully

ADV ANTHONY BRINK
CONVENER AND NATIONAL CHAIRMAN
TREATMENT INFORMATION GROUP

Cc: The South African government, all provincial Health MECs, media and other interested parties.

IMPORTANT POSTSCRIPT:

After gross irregularities both in the conduct of the HIVNET 012 nevirapine trial in Uganda and the US National Institutes of Health's subsequent attempt to whitewash them in its 'Remonitoring Report' were brought to the attention of the Oversight and Investigations Subcommittee of the Energy and Commerce Committee of the US House of Representatives in March this year, the committee ordered the National Institutes of Health to submit to an independent investigation of both the trial irregularities and the cover-up. The Institute of Medicine, a branch of the National Academy of Sciences of the United States of America, was tasked to carry it out in about June. Its website currently notes:

> At the request of the National Institutes of Health (NIH), the Institute of Medicine (IOM) is conducting an independent review of the HIVNET 012 perinatal HIV prevention trial. … The NIH has asked the IOM to review methodological and data interpretation issues related to protocol design, data collection, recordkeeping, quality control, and analysis. The committee will assess the impact of these issues on the validity of overall findings and conclusions of the trial.

On 21 September 2004 the National Whistleblower Center ('NWC') in Washington wrote to the IOM, raising rampant conflict of interest in the IOM panel, and other serious matters compromising the enquiry. A copy of its letter is annexed. (Two members of the panel reacted by resigning; the other issues remain to be resolved.)

The pressing local relevance of these developments in the US – even though Council has rejected both the HIVNET 012 study and the NIH's subsequent defence of it – arises from reference in the NWC's letter to a plethora of 'unreported adverse that were not recorded, as the principal investigators admitted to the Westat auditor' and the fact that 'the study physicians evaluated adverse events often on the basis of third hand descriptions from non-physicians and without personally examining all patients'.

HIVNET 012 is the study on the basis of which Council specially registered nevirapine as both safe and effective for administration to women in labour and their newborn babies in South Africa, and it was the lynchpin of the Treatment Action Campaign's successful case against our government in the High and Constitutional Courts, forcing it to supply the drug for this indication.

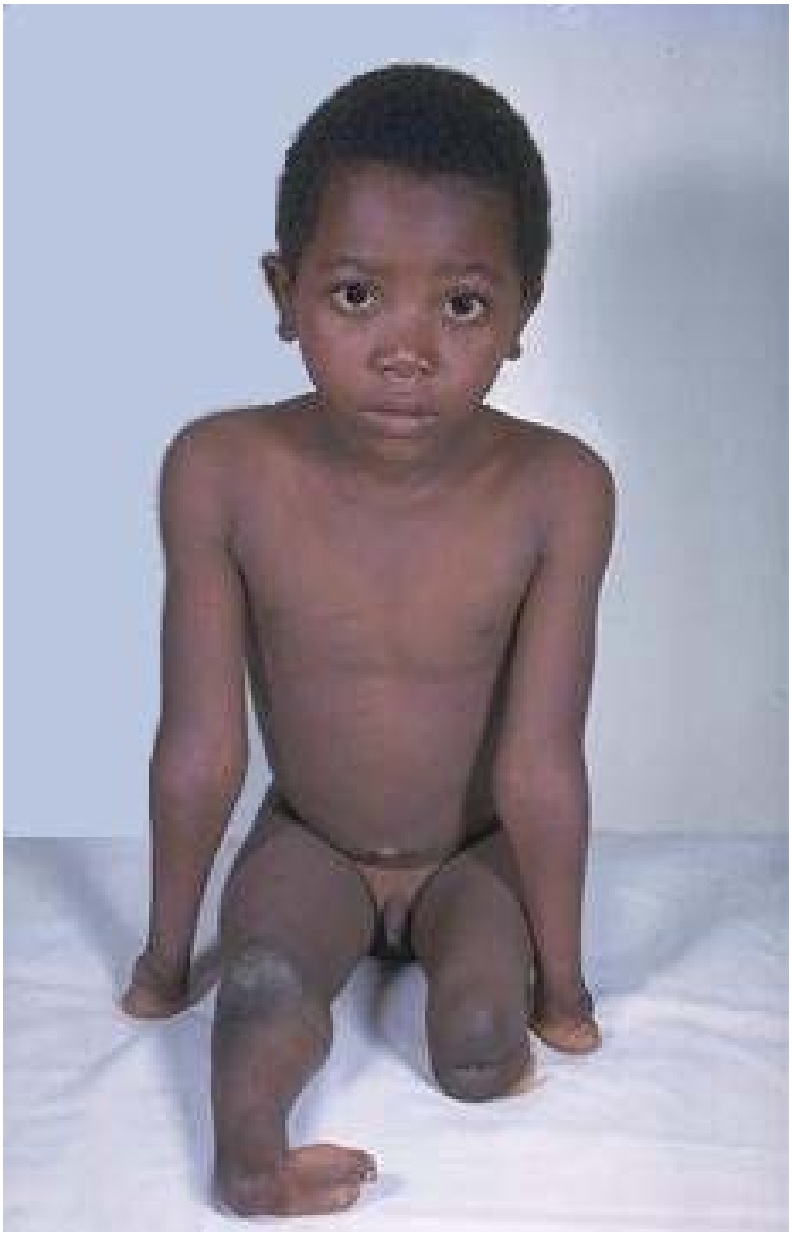
After subsequently rejecting HIVNET 012, as well as the NIH's attempt to save the study in its 'Remonitoring Report', Council put Boehringer Ingelheim on terms to come up with other evidence of safety and efficacy to warrant the continued special registration of the drug. The time allowed the company has long come and gone. In

our first letter in June we asked what Council was doing about this. We're still waiting to hear.

The HIVNET 012 trial overseers' admission that numerous adverse events went unrecorded, and that those adverse events that were recorded were often based on hearsay only, underscores the urgency of the need for Council to determine its review of its continued registration of nevirapine for even single-dose perinatal use. The safety data reported in HIVNET 012, on the basis of which Council specially registered nevirapine for perinatal use in South Africa, bad as they were, have turned out to be utterly corrupt.

The continued registration of the drug for perinatal use is indefensible. In the circumstances, why has Council not revoked the special conditional license it granted Boehringer Ingelheim to market nevirapine for administration to women in labour and their newborn babies?

Has everyone gone fishing?



Thalidomide victim

‘Distavel [*thalidomide*] can be given with complete safety to pregnant women and nursing mothers without adverse effect on mother or child. ... Outstandingly safe, Distavel has been prescribed for nearly three years in this country [*UK*]. … a harmless, safe and effective sedative with no side effects. … Harmless even over a long period of use … completely harmless even for infants.’ British Distillers (Biochemicals) plc *c.*1961.

‘The piperidinedione hypnotic thalidomide was responsible for thousands of children with disastrous defects such as absence of limbs. This occurred especially in Germany. Pregnant women ingesting a single hypnotic dose of the drug between the

twenty-fourth and thirty-sixth day of their pregnancy have delivered severely deformed babies.' *Medical Pharmacology*, Andres Goth, 9th edition, 1984