NEWS IN FOCUS

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New treatments could help to safeguard the health of infants like this baby, born to an HIV-positive mother in Uganda.

AFRICA

HIV trial under scrutiny

Critics say that antibody therapy is too expensive for its African target population.

BY MEREDITH WADMAN

A potential breakthrough in the quest to prevent HIV and AIDS has collided with sensitivities about testing expensive drugs in poor parts of the world. Three years ago, scientists at the US National Institute of Allergy and Infectious Diseases (NIAID) in Bethesda, Maryland, isolated a pair of potent monoclonal antibodies that neutralized more than 90% of the HIV strains that infect people (X. Wu *et al. Science* **329,** 856–861; 2010). Now, one of those antibodies, VRC01 (named after the institute's Vaccine Research Center, VRC), is being readied for a clinical trial in Africa.

But the proposed trial — in 3,000 African infants born to breastfeeding, HIV-infected mothers — is drawing fire from critics. They cite the therapy's steep cost and lack of proven efficacy in adults, and say that an affordable way to prevent mother-to-child HIV transmission already exists. Those points are likely to surface at a meeting in Entebbe, Uganda, on 22–23 January, where attendees will pound out principles for conducting prevention trials in breastfeeding babies born to HIV-positive mothers in poor countries.

One of those invited to the meeting, Arthur Ammann, president of Global Strategies for HIV Prevention in Albany, California, says that the trial would be testing a treatment on infants "that would never be available to them or anyone else in a resource-poor country". But Barney Graham, a senior investigator at the VRC and one of the leaders of the proposed study, asks: "If you have a product you think has a chance of preventing infection, is it ethical not to do that study?"

The impetus for the trial arises from a conundrum: breast milk protects infants from pneumonia and gastroenteritis, major killers in developing countries, but the milk can also transmit HIV. It is estimated that, in sub-Saharan Africa, 40–50% of the roughly 300,000 new infant HIV infections in 2011 were acquired through breastfeeding. But a cocktail of HIV-fighting drugs known as antiretroviral (ARV) therapy can substantially reduce the risk, so the World Health Organization recommends that HIV-positive women breastfeed their infants and that mother and baby both take ARV drugs.

However, ARV therapy is not perfect: infections break through at a rate of 2–5% by the time babies are six months old. The antibodies, which stop the virus from attaching to and entering human cells, offer hope, says ▶

Graham. "Can we get rid of that residual infection by adding an antibody, and would it work well enough to be cost-effective and logistically feasible?" he asks. The trial is designed to answer that question by giving the mother–baby pairs oral ARV therapy while half of the infants also receive monthly injections of VRC01. A control group would get a placebo.

The study will proceed only if VRC01 is approved as an investigational drug by the US Food and Drug Administration, and it would first be safety-tested in adults and infants in the United States. Investigators then hope to move to trial sites in Botswana, Malawi, South Africa, Tanzania, Uganda, Zambia and Zimbabwe. But the critics say that even if the antibody reduces the HIV infection rate, it is unlikely to be widely used in Africa. Whereas ARV therapy is delivered as oral tablets that cost less than US$200 per patient per year in poor and middle-income countries, the antibody must be injected by trained staff. In the United States, monoclonal antibody treatments commonly cost thousands of dollars per year.

Physician and AIDS expert David Ho of the Aaron Diamond AIDS Research Center in New York City is also planning to test an anti-HIV monoclonal antibody, but says that his group decided against running their trial in newborns after working in a poor area in southern China. There, he found that using ARV therapy as well as providing clean water and formula so that women do not have to breastfeed reduced mother-to-child HIV transmission to 1% (Z. Zhou *et al. J. Acquir. Immune Defic. Syndr.* **53** (suppl. 1), S15–S22; 2010). With a transmission rate that low, Ho says, "you are not going to be able to do a meaningful study". Instead, he is planning to conduct his group's prevention study in men who have sex with men.

But Graham says that discouraging breastfeeding, with its many health benefits, is not an acceptable route for reducing infection risk. And Catherine Hankins, deputy director of science at the Amsterdam Institute for Global Health and Development, says that it is premature to worry about cost. She points out that the basic ARV tablets used in Africa dropped in price from more than $10,000 to as little $140 annually in the past decade. "To say up front that something is too expensive, forget it — there are a lot of things we wouldn't have today if people had said that." ■

FINANCE

Insider trading sparks concerns

Universities indulge researchers' ties to finance industry.

BY HEIDI LEDFORD

It is as predictable as a heartbeat: when crucial medical results are at hand, cardiologist Jean-Luc Vachiery knows that the hedge-fund managers will come calling. Vachiery, who tests experimental therapies for a rare condition called pulmonary arterial hypertension at the Free University of Brussels, is privy to confidential information about clinical trials that could be valuable if used — illegally — to guide investments. As such, his conversations with the financial sector can be tense. "They tell you, 'don't say anything that's confidential'," says Vachiery. "And then they ask you for confidential information."

"This is not something that doctors or researchers should be involved in."

Vachiery, like about 35,000 academics, is a member of the Gerson Lehrman Group, based in New York, one of about 40 'expert network' companies proliferating in the United States and elsewhere that connect clients, often from the financial industry, with experts who can provide technical information. The company recruits heavily from academia and was reluctantly thrust into the limelight last year when one of its most prestigious experts — Sidney Gilman, a neurologist then at the University of Michigan at Ann Arbor — admitted to tipping off a hedge-fund manager about clinical-trial data before they were made public. The result: US$276 million in illicit gains for the hedge fund, the largest insider-trading case the US Securities and Exchange Commission (SEC) has ever handled.

The case is just one in a string of SEC probes launched since 2009 into whether expert networks are trafficking insider information to the financial industry (see 'Trading on expertise'). That investigation has already led to charges against nearly 30 people with connections to expert networks, and is continuing to yield fresh targets, particularly in the healthcare industry. It also highlights the tightrope that researchers walk when they consult for the financial industry, for rates that can reach $1,000 per hour. "The only reason anybody wants to talk to you from a financial company is for insider information," says Arthur Caplan, a bioethicist at New York University's Langone Medical Center. "That's the start of the story and that's the end of the story."

Despite the risks, few research institutions have enacted policies to limit staff consultations for the financial industry. Many universities, as well as the US National Institutes of Health, require investigators to disclose consulting income above a given threshold, but few distinguish financial consulting from consulting for drug companies. That's an important distinction, argues Eric Campbell, who studies conflicts of interest at Massachusetts General Hospital in Boston. "This is just a short-term bet for a very select group of people to make a whole lot of money," says Campbell. "This is not something that doctors or researchers should be involved in."

Even so, the networks and the experts they employ maintain that they are doing nothing illegal. Gerson Lehrman, like many other expert networks, has policies to prevent the exchange of confidential information, including a mandatory online training course, and pre-interview questionnaires to prevent experts with insider information from being matched with clients seeking information about that particular field. "All of this makes us a bad place to break the law,"

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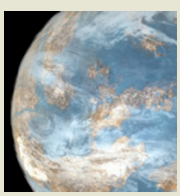

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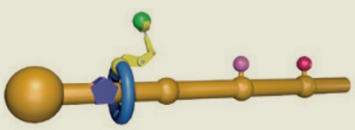

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