AIDS activists in Thailand pressurise US government

Gavin Yamey *BMJ*

A coalition of AIDS activists in Thailand, with the support of Médecins Sans Frontières, sought assurances from the US government this week that it would allow Thailand to produce its own cheap version of the antiretroviral drug didanosine.

The activists wanted the Thai government to issue what is known as a "compulsory licence" for the drug, but the government failed to do so.

The compulsory licensing system allows local manufacturers in poor countries to make cheap versions of patented drugs during public health emergencies, provided that they give a royalty payment to the patent holder. The system is consistent with the World Trade Organisation's patent laws, and it is seen by health activists worldwide as the best chance for poor countries to obtain essential medicines (4 December, p1455).

Previous attempts by developing countries to use compulsory licensing to manufacture essential drugs have been met by trade pressure from the United States, which has been keen to protect its own pharmaceutical industry (BMJ 1999;319:1521).

A US pharmaceutical company, Bristol Myers Squibb, owns the patent in Thailand for a tablet form of didanosine, but the price puts it out of the reach of most of the one million people in the country with HIV infection.

If the Thai government had issued a compulsory licence for didanosine, this would have set a precedent allowing other developing countries to follow suit.

On 17 January the AIDS activists, including the chairman of the Thai National Network of People Living with AIDS, handed in a letter to the US embassy in Bangkok addressed to President Clinton.

The letter states: "The Thai government appears unwilling to make any move on compulsory licensing for fear of creating a US trade backlash with threats of trade sanctions."

Although the Thai government has declined to issue a compulsory licence for a tablet form of didanosine, it will allow its own government pharmaceutical organisation to produce a powder form of the drug at about a third of the price of the patented tablet version.

David Wilson of Médecins Sans Frontières in Thailand said: "A compulsory licence would have been a better result for the developing world in general. If you look at Thailand and [didanosine] alone, this is a good result, but for the wider world it isn't." □

US relaxes its guidelines on herbal supplements

Scott Gottlieb *New York*

The US Food and Drug Administration (FDA) has relaxed guidelines for the sale of herbal supplements. Its decision has opened the way for manufacturers of vitamins, herbs, and dietary supplements to market their products for conditions such as morning sickness, hot flushes, and memory loss in ageing without first proving that they are safe or effective.

The decision marks the latest in a series of legal and regulatory victories for the dietary supplement business, which has been growing since Congress passed a law in 1994 that severely restricted the FDA's authority to regulate it.

Under the new law, manufacturers of dietary supplements can make claims about how their products affect the structure or function of the body, but they may not claim to prevent, treat, cure, mitigate, or diagnose a disease without prior FDA approval.

The move angered and surprised consumer advocates. "This is a snake-oil exemption," said Dr Sidney Wolfe, director of the Public Citizen's Health Research Group in Washington, "it's a complete cave-in to the industry."

Agency officials insist that the rule, which will take effect from 7 February, is an important part of their 10 year strategy to increase consumer confidence in the safety, composition, and labelling of vitamins, herbs, and other nutritional aids.

The new law is part of the Dietary Supplement Health and Education Act, which distinguishes between products that claim to "affect the structure or function of the body" and those that claim to prevent, treat, or cure disease.

The law allows the manufacturers of supplements to sell products without the FDA's rigorous safety and efficacy review that is required of drugs, as long as they make claims related only to structure or function and not to disease. □

Full story in News Extra at www.bmj.com

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Supplements from herbs will no longer be regulated by FDA

Drug companies seek MS patients to lobby for new products

Gavin Yamey *BMJ*

Schering Health Care, the manufacturer of the multiple sclerosis treatment Betaferon (interferon beta), is seeking the support of patients to lobby the National Institute for Clinical Excellence (NICE) before its ruling on the drug in May. The drug costs about £10000 ($16000) a year per patient, and many health authorities have been reluctant to fund it.

The company has launched a website (www.msvoice.co.uk) warning patients that "the only available pharmaceutical treatments for MS may effectively be withdrawn from use in the National Health Service." It also held a series of "phone-ins" at the end of last year, in which patients could speak to a doctor sponsored by the company.

Biogen, the manufacturer of Avonex (interferon beta), has also asked patients with multiple sclerosis to get involved in its Access to Action campaign to lobby health authorities.

But some patient representatives are concerned about the way in which drug companies are involving patients in their lobbying campaigns. Clara Mackay, senior policy researcher at the Consumers' Association, said: "We fully support campaigns which raise awareness of conditions that might otherwise leave people suffering unnecessarily, but the Consumers' Association questions whether it is appropriate for drug companies to lead these campaigns." The MS Society, the largest organisation for people with multiple sclerosis, believes that campaigns focusing on a single drug are misguided. David Harrison, the society's public relations adviser, said: "We do believe that beta interferons have been proven to make a significant improvement to the quality of life of some people with MS, but we are lobbying the government to ensure equal access to quality care which should include physiotherapy, pain control, and continence aids." □