WHO's attempts to eradicate polio are thwarted in Africa and Asia

Owen Dyer *London*

Outbreaks of polio in Yemen and Indonesia, and the threat of polio returning to troubled regions of Africa, have dealt a blow to the World Health Organization's polio eradication programme in what was meant to be the final year of a 17 year campaign.

A total of 63 cases of polio have been identified in Yemen, and last week four cases were confirmed in Indonesia.

Bruce Aylward, coordinator of WHO's global polio eradication programme, said that many of the patients in the Yemen were paralysed. "Since polio only paralyses at most one child per 200 people infected, 50 identified cases of paralysis would mean at least 10 000 infections," he said.

The strain of poliovirus causing the new outbreaks originated in Kano province in northern Nigeria. In 2003 Kano was the focal point of a Nigerian Muslim boycott of polio vaccination, after local imams claimed that the vaccine was part of a US plot to spread AIDS or infertility in the Islamic world (*BMJ* 2004; 328:485).

Several Nigerian provinces blocked immunisation for months before finally accepting a vaccine manufactured in

Indonesia. The boycott was followed by a large outbreak of polio in Nigeria and surrounding countries.

Dr Aylward no longer expects to meet the WHO target, set in 1988, of eradicating polio by the end of 2005. "We're still pretty confident about meeting the target in Asia, where they've had enormous success

recently. Previously, India was the main exporter of poliovirus. We haven't seen an Indian strain pop up abroad for two years."

But the 2003 Nigerian outbreak set back the campaign in Africa, he said. "Unfortunately the virus is now back in the surrounding countries. We're worried about much of western and central Africa and the Horn of Africa."

"We'll have a clearer picture after this summer, the high season for polio. Whatever happens, the low season of early 2006 will give us the chance to have a really good crack at it," said Dr Aylward.

"Twenty years from now, when polio is long gone, I don't think anyone will be worrying whether we missed the target by six months. The important thing is not to let up now that we're so nearly there. We have a \$50m (£27m; €39m) shortfall in funding for the rest of the year. If that's not made up somehow, we'll again have to abandon vaccination programmes in disease free areas. That's what we did last time we were short of funds, in the very areas where polio is now cropping up again."

The WHO polio eradication programme has cost \$4bn since 1988 and is credited with saving five million children from paralysis. □

A health official gives a polio vaccine to a boy in West Java after four cases of the disease were confirmed in Indonesia

New law aims to distance the FDA from the drug industry

Jeanne Lenzer *New York*

Legislation aimed at ending the close relationship between the US Food and Drug Administration and the drug industry was introduced last week in the House of Representatives by Congressman Maurice Hinchey (Democrat) of New York.

The Food and Drug Administration Improvement Act 2005 has been endorsed by the Center for Science in the Public Interest in Washington, DC, a non-profit education and advocacy organisation. Merrill Goozner, director of the centre's integrity in science project, said it was "exactly what is needed to restore

public confidence in the FDA."

The bill includes several provisions aimed at ending financial conflicts of interest. Drug companies would still be expected to pay fees but they would be paid to a general fund of the US Treasury. The bill prohibits the FDA from negotiating with drug companies about how it uses funds and it "terminates all previous agreements between FDA and such companies."

The bill would also prohibit scientists with financial conflicts of interest from sitting on FDA advisory panels.

Furthermore, it would establish a separate centre for post-market drug safety and effectiveness, so that "different doctors and scientists than the ones who approve a drug will monitor its safety once it hits the market."

If passed, the bill would overturn provisions of the Prescription Drug Users Fee Act (PDUFA), first passed in 1992,

which established a schedule of payments by the drug industry to the FDA.

Mr Hinchey said, "[PDUFA] was initiated during the first Bush administration, allegedly to speed up the approval of drugs, but what it did—and what I think they knew it would do—was to establish a close relationship between the regulatory agency and the industry it is supposed to regulate. Right now, almost 50% of the FDA drug budget is funded by the drug industry.

"And the ridiculous part is that the FDA has to negotiate with drug companies about how they use this money. It creates a relationship that is contrary to the whole idea of what the FDA is supposed to be."

The bill would redirect drug company fees to a general fund of the US Treasury and would create mandatory funding levels to support the FDA. It would also prohibit the FDA from negotiating with drug compa-

nies and "terminates all previous agreements reached between FDA and such companies."

Other provisions of the bill would empower the FDA to mandate post-marketing studies, demand label changes, and impose penalties of up to \$50m (£27m; €39m) against companies that violate FDA drug regulations.

A controversial legal stance at the FDA known as "pre-emption" (*bmj.com*; 8 Jan 2005, News Extra) that was introduced by the former chief counsel to the FDA, Daniel Troy, would also be reversed under the bill. Mr Troy argued that manufacturers of drugs that were approved by the FDA could not be held liable for adverse outcomes unless the company committed outright fraud.

The FDA does not comment on legislation. The Pharmaceutical Manufacturers and Research Association had not responded to requests for interviews at the time the *BMJ* went to press. □