Congress examines childhood vaccine safety

Sammy Sosa, a star baseball player for the Chicago Cubs, donated money last month to set up a clinic in his home country of the Dominican Republic. The clinic will vaccinate over 50,000 children a year. Having grown up in the abject poverty of the small Caribbean country, it seems that Sosa has a much better understanding of the value of immunization than some Congressional Republicans. The latter have held a series of hearings over the past few months to investigate vaccine safety and are perilously close to triggering public rejection of childhood immunization protocols.

The hearings, entitled "Vaccines: Finding the Balance Between Public Safety and Personal Choice," were spurred by parents who believe their children were harmed by routine immunizations, and by military personnel concerned about the safety of anthrax vaccines they have been ordered to receive.

Two subcommittees of the Committee on Government Reform held hearings on vaccine adverse reactions in May and the full committee, chaired by Congressman Dan Burton (R-IN), took up the issue on August 3rd. Burton is a proponent of alternative medicine who believes that two of his grandchildren have suffered serious adverse effects from hepatitis B vaccination.

The hearings and their attendant publicity appear to have become increasingly dominated by political concerns and special interests, at the expense of sound science. Aside from Surgeon General David Satcher, and Samuel Katz, who represented the American Academy of Pediatrics and the Infectious Diseases Society of America, the only witnesses were parents who claim their children were injured by vaccines, and outspoken critics of mandatory vaccination.

Safety fears have been heightened by the news that the first vaccine designed to prevent rotavirus infection was suspended only 11 months after it was approved by the US Food and Drug Administration (FDA), following 20 reported cases of intussusception in infants. Data on the potential link between the vaccine and intussusception, a type of bowel obstruction, are expected to be released within a few months.

Public health experts in the US now worry that the safety debate could have disastrous consequences, such as those seen in France, where officials suspended hepatitis B immunization in the face of public pressure (*Nature Med.* **4**, 1217; 1998), and in the UK, where parents refused the combination measles–mumps–rubella vaccine for their children following an autism scare (*Nature Med.* **5**, 478; 1998).

Dan Burton

In addition to the alternative healthcare and herbal supplement industry, Katz explains that "there's a whole other element which has allied itself to the cause and that is the more libertarian approach of 'why are our children required to have these vaccines, shouldn't it be freedom of choice?'" Some opponents of mandatory vaccination also claim that the pharmaceutical industry exerts undue influence over the Centers for Disease Control and Prevention (CDC) and the FDA, an issue that the committee is investigating.

Among those asserting that the CDC has a conflict of interest is Bart Classen, a physician and president and sole employee of Classen Immunotherapies, Baltimore, MD. At the May hearings, Classen testified that CDC data supports a causal link between the timing of hepatitis B vaccination and Type I diabetes. "No one's disputing the data. What's controversial is how the public health service is trying to deny it all," says Classen.

The CDC takes a different view. In a one-page report containing the data CDC researchers concluded that the possibility of such a link "cannot be ruled out and will require larger more detailed studies," (*Pharmacoepidemiology and Drug Safety* **6**, S60; 1998), suggesting that although the data may not be in dispute, their interpretation clearly is. Classen owns patents on several vaccine-testing protocols which would likely be required if legislators are persuaded to accept his interpretation of the study.

Although no specific legislation has been proposed, committee staffers say that industrial procedures for vaccine testing and the possible removal of limits on vaccine manufacturers' civil injury liability are also key issues of evaluation.

ALAN DOVE, NEW YORK

India fast-tracks vaccine candidates

The Indian government has launched an ambitious project to develop and manufacture new 'home-grown' vaccines against several communicable diseases within three years for just $4 million.

The initiative marks the first time that the government has allocated funding specifically for vaccine R&D and entrusted the task to a particular agency—the Department of Biotechnology (DBT). The project will fast-track vaccine candidates identified by government laboratories for malaria, tuberculosis, cholera, Japanese encephalitis, rabies and AIDS.

The initiative comprises 12 basic research institutions that have researched potential vaccines over the last two decades, plus two biotechnology companies based in Hyderabad—Indian Immunologicals and Bharat Biotech. Until now, institutes received vaccine R&D allocations within their budgets, "but the scattered research projects failed to produce anything beyond publications," says N.K. Vinayak, who heads DBT's medical division.

DBT secretary Manju Sharma says that the targets were chosen based on the existence of promising leads in these areas. For example, an oral recombinant cholera vaccine developed at the Institute of Microbial Technology in Chandigarh passed Phase I trials last year, and the DNA rabies vaccine developed at the Indian Institute of Science in Bangalore, plus a vaccine against the Indian strain of Japanese Encephalitis virus developed at the National Institute of Immunology, New Delhi, are in late-stage preclinical trials. Sharma anticipates that the vaccines against cholera and rabies will become available for use in the healthcare system at the end of the program in 2002.

Although India has only a limited HIV vaccine research program, the government felt that this should be included in the initiative because "sustained R&D efforts are required to develop a vaccine against the subtype-C virus prevalent in India, rather than the subtype-B vaccines being developed abroad." This work is being done at the All India Institute of Medical Sciences in New Delhi, where a "modified pox virus construct expressing genes of the HIV-1 subtype-C will be ready for animal trials 12 months from now," according to Vinayak.

K.S. JAYARAMAN, NEW DELHI