

## RotaShield returns

The oral rotavirus vaccine RotaShield is to be resurrected in the USA, 5 years after it was withdrawn. The US National Institutes of Health (NIH), which had an exclusive licensing agreement with the original manufacturer, Wyeth, has announced a new agreement with BIOVIRx (Minneapolis, MN, USA), which plans to market the vaccine worldwide. The licensing agreement "is aimed at helping to prevent hundreds of thousands of deaths annually from rotavirus diarrhoea in children in developing countries".

RotaShield, the first and so far only rotavirus vaccine, was licensed in the USA in 1998 and recommended for the immunisation of all American infants. However, the vaccine was withdrawn in

1999 because of a perceived link with intussusception. The new agreement follows a reappraisal of the risk by NIH scientists (*J Infect Dis* 2003; **187**: 1301–08), who found an overall reduction in risk among vaccinated infants up to 1 year old, despite a small excess risk (1 in 32 000) at age 1.5–7 months, against a background risk of 1 in 3000. The authors concluded that the result of RotaShield withdrawal was "no overall gain, only loss". What was gained by not using the vaccine—ie, prevention of an excess of intussusception—was "extremely small in comparison to the losses incurred in both the USA and, particularly, in developing countries, where up to 520 000 infants die annually from

severe rotavirus diarrhoeal disease". Moreover, the withdrawal of RotaShield's use in infants makes further studies of the vaccine "extremely difficult". This, the authors say, "is especially troubling when one considers the urgent need for its use in the developing world".

More than a million doses of RotaShield were given before the vaccine was withdrawn, and at present there is no alternative vaccine. According to Brian Murphy, a co-author of the NIH study, there have been about 1.75 million preventable deaths due to rotavirus since RotaShield was withdrawn, assuming universal availability of the vaccine.

**Dorothy Bonn**

## CDC reorganisation begins

In May, US Centers for Disease Control and Prevention (CDC; Atlanta, GA) director Julie Gerberding announced the creation of four new coordinating centres as well as the Office of Global Health at the CDC. Additionally, she identified goals and strategic imperatives for the agency.

"We want to make it easier and more effective for the CDC to meet the demands of our customers", agency spokesperson Tom Skinner told *TLID*. The announcement evolved from the Futures Initiative, which began a year ago at the CDC and emphasised a corporate model to modernise CDC management and business practices.

The CDC includes 12 centres, institutes, and offices, which were clustered as part of the first step in the reorganisation of the agency. Mitchell Cohen has been named director of the Coordinating Center for Infectious Diseases, which brings together the National Center for Infectious

Diseases, the National Immunization Program, and the National Center for Sexually Transmitted Disease, Tuberculosis, and HIV Prevention.



Mitchell Cohen

Pat McConnon, executive director of the Council of State and Territorial Epidemiologists (Atlanta, GA), has spoken with members about the reorganisation and most have called the proposed organisational structure rational. "It makes sense to them in terms of the way state health departments, particularly epidemiologists, would view the groupings of diseases and conditions; for example, putting all the infectious disease groups together at CDC under one umbrella will be quite helpful", he told *TLID*.

As part of her announcement, Gerberding also identified two overarching goals for the CDC: preparedness, and health promotion and prevention of disease, injury, and disability. Six strategic imperatives were also identified, ranging from "CDC will become a customer-centric organisation" to "global health".

In the USA, CDC grants provide a healthy portion of funding for state and local health departments. According to McConnon, the grants management office of CDC became outstripped in the early 1980s; for example, funds were not made available to states when needed and last-minute decisions on requests for grant extensions to states were common. "Everyone applauds the agency's restructuring commitment to focus internally on the procurement and grants piece", he said.

"Improving our business practices and the way that we manage grants at CDC with the state and local health departments and our other partners, making the process easier and more effective, are all a big part of the Futures Initiative", Skinner told *TLID*.

McConnon hopes the changes in grants management are "really substantive" and encourages the CDC to seek substantial input and objective assessments of their practices from outside sources.

The CDC plans to implement these changes by October 1, 2004, the start of the next fiscal year.

**Mary Quirk**