

New law offers drug makers sweeping protection against lawsuits

Two gifts for pharmaceutical companies lie nestled in this year's defense spending law. The first is \$3.8 billion, much of which will go toward developing drugs and vaccines for avian flu. The second, dubbed 'targeted liability protection,' could benefit the industry even more in the long term.

In language folded into the bill at the last minute by Republican Senator Bill Frist, makers of drugs and vaccines used during a public health emergency, such as an avian flu outbreak or a bioterrorism attack, would not be liable if someone who took those products were to become ill or die. Instead, the government would offer compensation to those individuals. A compensation fund has already been established, but is not yet stocked with money.

The idea is to tempt risk-averse private compa-

nies, and the venture capital that funds some of them, into investing in infectious diseases. In the past few decades, the number of firms that make vaccines for the US market has fallen from about 30 to just 4. According to Amy Call, a staffer in Senator Frist's office, the decline is a direct result of patient lawsuits. "It's all due to liability," Call says. "This [law] is necessary to get companies back on the market."

Some Democrats have derided the law as a giveaway to drug companies. Senator Edward Kennedy notes that all that is required to trigger the liability protection, according to the language in the law, is for the government to declare a public health emergency. In theory, he warns, declaring an 'arthritis epidemic' could get controversial painkillers such as Vioxx off the hook.

That scenario might be unlikely, but a real

concern is that the compensation fund is empty, notes Michael Stebbins, director of biology policy at the Federation of American Scientists. "As far as I know, there has been no scientific study as to what would be needed in such a compensation program," Stebbins says.

A similar scheme for emergency and health workers who received the smallpox vaccine included a fund stocked with cash. But supporters of the new law say that because the scope of a future health crisis is unknowable, it is more sensible to stock the fund when it happens.

President Bush signed the bill into law just before the new year. Makers of vaccines and drugs, who had been working on similar legislation for at least a year, are reportedly happy with the new law.

Emma Marris, Washington, DC

Side benefits sway developing nations to choose unneeded vaccines

Global health agencies provide welcome funds and health supplies to the poorest of countries. But in some cases, these agencies are imposing unnecessary vaccines and drawing the focus away from more pressing health problems, critics charge.

In the past few years, agencies such as The Global Alliance for Vaccines and Immunization (GAVI) have made vaccines accessible to developing countries. The packages are attractive: apart from the vaccines, the organizations provide other health supplies and the funds to help deliver vaccines. For many resource-poor governments, the offer may be too good to turn down, even if the vaccines are not warranted by disease prevalence.

"Global health initiatives are distorting country priorities, sometimes getting health ministries to give priorities to vaccines they would not have normally considered," says David Sanders, director of the school of public health at the University of the Western Cape in Zambia.

For example, Sri Lankan scientists in 1998 advised their government not to accept Italy's offer to introduce a vaccine for hepatitis B, which has less than one percent prevalence in the country. The regional World Health Organization office recommends that the vaccine only be included in routine immunization when the prevalence exceeds two percent.

But in 2002, Sri Lanka opted for support from GAVI, a public-private partnership launched in 2000. "GAVI offered a better package of disposable syringes and waste



Shot down: Global health agencies may support vaccines for diseases of low prevalence.

disposal," says Nihal Abeyasinghe, director of epidemiology in Sri Lanka's ministry of health.

India also similarly accepted hepatitis B vaccines supported by GAVI, even though the disease's exact prevalence in India is unknown, with estimates ranging from 1.4 to 4 percent.

"The vaccines that are being offered are often not what the countries would choose on their own, nor do they reflect their chief concerns," says William Muraskin, professor of urban studies at the City University of New York and author of a book on GAVI.

But representatives of GAVI say it is up to the individual countries to set health priorities. "GAVI does not push decisions and vaccines on countries," says Jean-Pierre Le Calvez, a Paris-based GAVI spokesperson.

In December, GAVI launched a global

initiative for vaccination against *Haemophilus influenzae* B (Hib), which each year causes about 400,000 deaths, mainly in children under age five.

Ghana does not have data on its Hib prevalence but is already offering the vaccine.

In 2001, Ghana faced a delay in the availability of a combined vaccine for diphtheria, pertussis, tetanus and hepatitis B. Given a 10-day deadline by GAVI to choose an alternative, Ghana opted for a more expensive vaccine that also included protection against Hib (*Lancet* 359, 435–438; 2002).

Such decisions draw valuable resources from more urgent health problems, critics say. Some public health analysts have also criticized these agencies for focusing too much on high-tech vaccines and not enough on building the infrastructure to deliver the vaccines (*Br. Med. J.* 331, 755–758; 2005).

In Africa, coverage of basic vaccines has stagnated since the 1990s because of a lack of infrastructure, says Sanders. Unless delivery systems in Africa are strengthened, he says, introducing more vaccines is meaningless. "So why not put more money for improving the health system?" he asks.

Responding to such criticism, GAVI is doubling the proportion of its budget for health systems support from 25% to 50%, adding up to US\$500 million over the next ten years. It also plans to improve its coordination with governments, placing more emphasis on the countries' input and budgets.

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