

US anti-bioterror efforts swiftly expanding

Responding to a limited but deadly series of deliberately inflicted cases of anthrax that followed the September 11 attacks, US officials and industry representatives established special task forces and announced collaborative efforts to fortify national readiness against further bioterrorist attacks. And, amid a flurry of additional bioterrorist defense-related developments, President George W Bush also pledged to reexamine ways to strengthen the Biological Weapons Convention (BWC), veering away from a decision shortly before the September incidents to reject a proposed treaty for strengthening restrictions on bioweapons development and use (*Nat. Biotechnol.* 19, 793, 2001).

"The United States is committed to strengthening the BWC as part of a comprehensive strategy for combating the complex threats of weapons of mass destruction and terrorism," Bush said in November. "The ideas we propose do not constitute a complete solution to the use of pathogens and biotechnology for evil purposes. However, if we can strengthen the convention against the threat of biological weapons, we will contribute to the security of the people of the United States and mankind as a whole." He recommended taking several steps, but steered clear of any measures that might entail industrial or research facility inspections, whose prospects were considered pivotal in his earlier decision to reject the proposed treaty.

Meanwhile, despite persisting uncertainty about the source of the anthrax attacks, US officials are accelerating efforts aimed at protecting the public more broadly against these and other even more worrisome bioterrorist agents. Not only are they expanding the scope of their preparedness against such agents, but they also are planning in a more focused fashion to rebuild supplies if it proves necessary to vaccinate the public against smallpox, a disease that several decades ago was "eradicated," at least insofar as it once circulated naturally.

Surely with such threats in mind, Department of Health and Human Services (HHS) Secretary Tommy Thompson in November appointed Donald Henderson, who led the World Health Organization's smallpox eradication campaign from 1966 to 1977, to head the new HHS Office of Public Health Preparedness. Henderson's responsibilities will entail coordinating the national response to public health emergencies—improving focused health-monitoring programs and seeing to other efforts



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intended to deter bioterrorist attacks. Henderson comes to HHS from Johns Hopkins University (Baltimore, MD), where he directed its Center for Civilian Biodefense Studies.

Also joining HHS as a special advisor on vaccine development and production is Phillip Russell, a former director of the US Army Medical Research Institute of Infectious Diseases (USAMRIID; Frederick, MD), a major center for bioterrorist defense research and related activities. And, at the Food and Drug Administration (FDA; Rockville, MD), Janet Woodcock, who has been director of the FDA Center for Drug Evaluation and Research, was temporarily reassigned for full-time counterterrorism coordination duties, helping to smooth cooperative efforts between FDA and other federal agencies and to ensure that FDA has contingency plans for a variety of terrorist scenarios.

One important challenge facing these recently appointed and reassigned federal officials is to work effectively with members of the biotechnology and pharmaceutical industries to produce adequate supplies of drugs and vaccines (or, in some cases, develop new products) that might be needed to counteract or prevent specific bioterrorist agents. Both the Biotechnology Industry Organization (BIO; Washington, DC) and the Pharmaceutical Research and Manufacturers of America (PhRMA; Washington, DC) recently established special task forces dedicated to meeting these same needs—and also, to some extent, educating their own member companies about how best to contact appropriate government agencies and how to expedite negotiations with them.

Some of these efforts focus on a sharply increased demand from government officials for reliable information. BIO, for example, recently formed a seven-member team to respond to stepped-up recent requests from officials in federal agencies and Congress for accurate and sometimes technical information on bioterrorism-related subjects, including how the biotech industry can help in meeting such threats. In addition, BIO is establishing a permanent committee for dealing with public health and vaccine-related issues, whose scope includes but extends beyond those identified as part of the immediate bioterrorist threat.

Amid these pragmatic steps, BIO also issued a formal statement, reaffirming its policy "opposing the use of biotechnology to develop weapons," while reminding the public of its central mission "to improve and save lives." In similar fashion, PhRMA president Alan Holmer said that, in the face of bioterrorist threats, the "pharmaceutical industry will do everything it can to help protect the public health." Members of its recently formed top-level task force on emergency preparedness have been meeting with federal officials to discuss antibiotic supply and production needs as well as plans for producing smallpox and other vaccines.

Along these same lines, the governing council of the Institute of Medicine (IOM), which is part of the National Academy of Sciences (Washington, DC), recommended in early November that a public-private sector "National Vaccine Authority" (NVA) be created. Its mission would be to "advance the development, production, and procurement of new and improved vaccines of limited commercial potential but of global public health need."

The new IOM recommendations speak specifically to the current threat of bioterrorism as well as the "larger national need for mechanisms to obtain public-good vaccines on an ongoing basis, and not just under extenuating circumstances." Moreover, according to the members of the IOM council, "An especially important function [of NVA] would be to provide opportunities for the production of pilot lots of vaccines developed by small biotechnology firms, and to produce vaccines when market forces are not sufficient to facilitate large-scale production." BIO representatives have expressed similar views during recent congressional hearings, emphasizing the need for long-term commitments from the government for vaccines, particularly those to protect against bioterrorist attacks, for which there is ordinarily little—or, in the case of smallpox, no—market demand.

Jeffrey L. Fox, Washington, DC