US federal bureaucracy hampers progress in countering bioterrorism

Despite considerable conviction, widening opportunities, and earnest willingness among biotechnology companies to join forces with the rapidly expanding, federally directed bioterrorism countermeasures buildup, a good deal of frustration continues to beset participants on both sides of this concerted effort. Although several members of Congress are proposing measures to overcome many of the assorted stumbling blocks, neither legislative nor administrative strategies for expediting matters appear particularly well suited to solving problems quickly.

In March, Senators Ron Wyden (D-OR) and George Allen (R-VA) introduced the "Science and Technology Emergency Mobilization Act," S. 2037, which would authorize the creation of a central clearinghouse for technology aimed at countering terrorism, including bioterrorism. If enacted, it would provide a single federal entity where companies and agencies within the US Department of Defense (DoD; Arlington, VA), the US Department of Health and Human Services (DHHS; Washington, DC), and other federal departments could exchange know-how, information about promising technologies or near-term products, and ideas for meeting anticipated needs. The legislative proposal also seeks to establish a "test bed" for initial evaluation of ideas and technologies from the private sector.

"It's bizarre to have [biotechnology companies] traipsing all over the government to find out where they have to go," Sen. Wyden said during a one-day conference, "BIO-Defense and Homeland Security," convened by the Biotechnology Industry Organization (BIO; Washington, DC) on April 30 and held a short distance from the Pentagon. "The government has got to be a better partner with you. Too often, biotech companies that want to sprint … have to run a marathon."

Industry representatives generally agree that a centralized federal technology clearinghouse for recognizing and funding development of bioterrorism countermeasures would be valuable. But they also see other areas where similar centralizing efforts would be useful, if not essential.

For example, federal procurement practices also should be centralized and made more systematic and uniform, and the entire process (particularly at DoD) should be expedited, according to Leighton Read, general partner at Alloy Ventures (Palo Alto, CA), who also spoke during the BIO conference. Such changes are needed particularly "to help small companies," he says, noting that prolonged contract negotiations and other more mysterious silent periods, during which proposals seem to disappear within the Pentagon or other federal bureaucracies, can prove devastating to research-based companies that are accustomed to rapid-fire decision making.

Leighton Read says small companies would benefit if federal procurement practices were centralized and made more systematic and uniform, and if the entire process were expedited.

Read also calls for the establishment of a National Vaccine Authority, reinforcing recommendations in a recent report from the Institute of Medicine (Washington, DC). Although details for the design of such a body are vague, the idea is to centralize authority over vaccine development and also to guarantee markets for certain vaccines, such as those that protect against anthrax, for which little or no independent demand exists outside of that arising from the threat of bioterrorism attacks. Currently, federal vaccine development efforts are shared among several federal agencies within DHHS and in the DoD—whose efforts are particularly fragmented, he says, citing a task-force report done for the DoD last year that reviewed its anti-bioterrorism programs in place before September 11 and the anthrax incidents that ensued.

Even before September 11, Pentagon officials were seeking better ways to integrate biology into overall defense efforts and to forge stronger ties with the biotechnology industry, and those fledgling efforts have subsequently accelerated, says BIO president Carl Feldbaum. BIO's member survey from that period netted more than 400 positive responses from biotech companies regarding ongoing or forthcoming biodefense capabilities, he notes.

"Prior to 9/11, only one or two dozen [biotech] companies dealt with DoD, a very small percentage," Feldbaum says. "But afterward, there was a surge of interest—perhaps a tripling of companies getting involved—followed by a cooling off when companies realized how difficult it is—some people complained bitterly of the lack of responsiveness from the Pentagon." Some of the companies are offering technology that goes beyond the expected drugs and vaccines that aim rather narrowly at countering bioterrorism attacks, he says. They are also working on, for instance, detection devices, new biopolymers, physiology- and performance-enhancing products, and schemes for producing energy.

But when it comes to biotech companies and the Pentagon or other federal partners actually working together, the would-be partners more often than not face a clash of cultures, according to Feldbaum and others. Biotech companies "are used to getting deals done," he says. The companies are finding, however, that "defense contracting is a mystery and hindrance" and that "there is no clean way to plug all those ideas, projects, and products into the government, either at the Pentagon or DHHS."

Implementing Sen. Wyden's proposals for a central clearinghouse and other measures to cut through bureaucratic thickets would help to bridge some of those cultural gaps, Feldbaum says. But other pending legislative proposals also need to be implemented. For example, S. 1764, the "Robert Stevens, Thomas Morris Jr., Joseph Curseen, Kathy Nguyen, Ottilie Lundgren, and Lisa J. Raines Biological and Chemical Weapons Research Act," which was introduced by Sen. Joseph Lieberman (D-CT) late last year, addresses several concerns facing biotech companies that seek to work with the Pentagon and other federal agencies on antibioterrorism projects. Specifically, it provides tax incentives, guarantees intellectual property rights, and protects against certain product liability claims.

In addition to these legislative reforms, the success of biotech-company collaborations with DoD and other federal agencies will depend greatly on new leadership at the Food and Drug Administration (FDA; Rockville, MD), Feldbaum continues. Agency officials are framing new rules for evaluating new vaccines, such as those against smallpox, that cannot ethically be tested for efficacy in humans. Nonetheless, with such an array of products to be evaluated, other organizational reforms needed, and important legislative issues pending, the president's nomination for FDA commissioner seems long overdue. "Recently we spoke with Vice President [Dick] Cheney's people, telling them the distance between the government and the biotechnology industry is a chasm that we've got to bridge," Feldbaum says, referring again to the gap in cultures that forestalls progress in meeting bioterrorism countermeasures needs. "It ain't going to be easy, but it's got to be done."

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