US officials clash with industry executives over BWC

Heightened interest in biological warfare issues among top US officials—including some in the arms control and disarmament agency and the department of defense—is leading them rather abruptly to champion international treaty-enforcement negotiations. However, despite recent jawboning with industry leaders, the debate about biological warfare enforcement measures seems headed sooner or later toward a familiar impasse and, hence, an inevitable political battle: In addition to the lack of unity within the government concerning the issue, industry representatives still see the notice and inspection protocols as more conducive to encouraging industrial espionage than to catching biological warfare evildoers.

During the State of the Union address early this year—and much to the surprise even of many officials within the administration—US President Bill Clinton referred specifically to the 1972 Biological Weapons Convention (BWC) and set a tight 1998 deadline for negotiating a "compliance and transparency protocol" to enforce the treaty. As part of these negotiations, a US delegation is scheduled to meet in Geneva later this month with representatives from other nations that make up a multinational ad hoc group.

Because the BWC—which Clinton says "lacks teeth"—has no formal compliance or enforcement procedures, it currently amounts to "hortatory arms control," says Gary Samore, a special assistant to President Clinton and a member of the National Security Council (NSC; Washington, DC). To strengthen the treaty, Clinton and NSC officials are intent on establishing an enforcement protocol, one that is expected to support a system of declarations and on-site inspections to facilities suspected of developing, producing, or storing biological warfare weapons (*Nature Biotechnology*, 16:14, 1998).

Arms control experts and industry representatives admit to being puzzled over the Clinton administration's sudden surge of interest in fortifying the BWC. To be sure, during the past several months, Clinton and his top advisors have been dealing with biological warfare issues with unusual frequency (*Nature Biotechnology* 16:327, 1998). For example, tense negotiations over whether UN inspectors could continue to inspect suspected Iraqi biological warfare weapons production and storage sites brought the Clinton administration to the brink of military action in the Middle East earlier this year.

Less well known is that, around the same time in March, top US administration officials, including NSC Director Sandy Berger and Commerce Department Secretary William Daley, hastily summoned more than a dozen biotechnology and pharmaceutical industry leaders from such companies as Eli Lilly (Indianapolis, IN), Johnson & Johnson (New Brunswick, NJ), OraVax (Cambridge, MA), and Novo Nordisk (New York) to a White House meeting, primarily to discuss the BWC compliance issues that will be on the table in Geneva.

For such high-level federal officials to engage their industry counterparts represents a significant escalation of these BWC negotiations at the domestic level as well as an important shift in momentum. Coming as it did amid ongoing tensions involving Iraq and some unsavory domestic biological warfare-related activities, the atmosphere was not conducive for industry representatives to object strenuously to newly formulated administration policies.

Industry representatives still see the notice and inspection protocols as conducive to encouraging industrial espionage.

Before this tête-à-tête, a working group with expert knowledge about the technical ins and outs of biological warfare arms-control issues had been meeting on a regular basis to evaluate some of the ingredients needed in a compliance protocol. This working group is led by the NSC and comprises representatives from federal agencies, universities, and industry, including the Biotechnology Industry Organization (Washington, DC) and Pharmaceutical Research Manufacturers of America (Washington, DC). Although the meetings are said to have been cordial and business-like, they have not marked rapid progress.

Catapulting the internal negotiations from the working group to the CEO level has moved the discussions away from those with immediate hands-on expertise, and also markedly raises the political stakes of the discussion while obscuring some of the disagreement that exists within the ranks both inside and outside the government. Some federal officials are said to be both dazed and disgruntled over this sudden shift in BWC policy toward this new enforcement regime. Some of them are more than a little skeptical that a declarations-and-inspection protocol can be implemented at public sector facilities—including Department of Defense sites and other federal laboratories—let alone in industry or at universities, without causing a great deal of havoc and also revealing more about the US biological warfare defensive capabilities than seems prudent.

Meanwhile, industry representatives remain cautious, perhaps remembering the 1994 trilateral biological warfare confidence-building exercise, which also involved the United Kingdom. Several impromptu "voluntary visits" then by Russian scientists to US pharmaceutical industry facilities proved so intrusive and defamatory for Pfizer (New York), which was falsely accused of continuing biological warfare operations, that the entire trilateral project subsequently dropped into oblivion. Its lingering memory has prompted at least one industry CEO to protest this new round of Clinton and NSC-driven efforts, but whether others will join the chorus is not obvious.

Nonetheless, some observers predict that, even if the US delegation convinces the other members of the multilateral ad hoc group to accept an enforcement protocol in Geneva this summer, the Clinton administration will still be faced with a corrosive battle when those proposals are brought back for the US Congress to consider.

Jeffrey L. Fox

Drug bill cuts force firms overseas

Japan's flagging National Health Insurance (NHI) system is ready to face full-scale renovation after the government recently took a significant step toward the introduction of a new reference price system that will set drug prices at more competitive rates.

This April, Japan's Ministry of Health and Welfare imposed a 9.7% cut in NHI drug prices as part of their measure to save ¥200 billion (US$1.5 billion) of medical expenses during the current fiscal year. The price cut is part of the Ministry's measures to contain annual growth rates for drug spending below 2% until the year 2000, when the reference price system is introduced.

The main aim of the reference pricing system is to eliminate "yakkasa," or the gap in price between the NHI reimbursement tariff