BIOLOGICAL DEFENSE PROJECT SUMMARY AND STATEMENT OF PURPOSE

It has long been recognized that the 1972 Biological Weapons Convention needs to be strengthened in order to be made more reliably effective. The convention formally prohibits the preparation and actual use of biological agents for offensive purposes but necessarily allows the development of defensive and therapeutic measures. With regard to research and development activities, the distinction is inherently difficult to draw, and there are no generally agreed standards for doing so. Moreover, there is an unresolved legacy of suspicion that is currently compounding the inherent difficulty. The military establishments that have historically been most intensely involved in investigating the potential of biological agents as instruments of warfare have been unable to establish a working presumption of mutual compliance with the BWC. In particular, there is a serious dispute at the moment between Russia and the United States. Russia firmly maintains that the offensive development program acknowledged to have been conducted by the Soviet Union has been terminated and that Russia itself has never violated the convention. The United States does not accept that assurance. Efforts to arrange a program of mutual inspection of facilities that might help to resolve the issue have not succeeded, and those who have been involved in that official effort are pessimistic about the prospects.

In response to this situation the United States National Academy of Sciences is attempting to develop a collaborative initiative with Russian colleagues that is intended to provide a constructive basis for resolving the historical problem and for generally strengthening the BWC. The basic idea is to design an institutionalized arrangement for conducting joint research and managerial oversight of the most dangerous human pathogens. The arrangement would be primarily directed to the public health problems associated with these pathogens but would also provide the most promising basis for assuring effective implementation of the BWC.

enhancing transparency by

The specific initiative being undertaken will outline a program of joint research designed to enhance the protection of human populations against any naturally occurring or deliberately induced outbreak of the diseases caused by the pathogens in question, and it will conduct a small number of specific joint projects with Russian colleagues designed to demonstrate the benefits of combining the established expertise of the two countries. The initiative will also outline the institutional provisions that would be required to sustain systematic research collaboration, to provide for joint reaction to any actual outbreak of the diseases of concern, and to establish common regulatory practices for preventing deliberate misapplication of the critical pathogens.

THE BASIC DESIGN

The idea for this initiative is derived from an appreciation of the special difficulty and special opportunities that arise in attempting to control the danger of biological weapons.

The special difficulty emerges from the fact that biological agents unlike standard weapons are generated naturally. In the first instance, their existence does not depend on a design bureau or a manufacturing organization. Moreover, most of the relevant information about biological agents is generated by medical science and is inherently and unavoidably available throughout the world. So are the pathogens themselves. As a result, dangerous development and production activities could in principle be undertaken in virtually any country with small scale operations that are readily concealed. These features of the situation preclude reliance on a system of control patterned on those developed, for example, for fissionable materials or for major items of military hardware. Security classification of information and the licensing of access to materials are not reliable means of controlling biological agents.

There are, however, some advantages. Biological agents are not the weapons of choice for tactical application by a fundamentally capable military establishment. Whatever questionable activities might have occurred historically in what is now Russia or in the United States, there is no reason to believe that either of their military forces ever made such an extensive commitment to the development of these weapons or ever developed such an important operational reliance on them that effective eradication of residual offensive capability is the equivalent of radical surgery. In reality both societies and both military establishments are far more plausibly threatened by small state or terrorist use of biological agents than they are by each other. They therefore have a common security as well as public health interest to build upon. Moreover, in the international community as a whole, there is a general aversion to biological weapons that provides a potentially powerful attitudinal foundation for the BWC. Since no country or organization can afford to be truly ostracized in the globalizing economy, operational rules and the incentives to uphold them can be quite effective when they are based on a broadly accepted moral and legal standard. And finally anyone who works with the most dangerous pathogens and survives the experience will have to have had some exposure to advanced training and therefore to the scientific community that conducts the training. As well as conveying relevant information the scientific community can embody consequential norms.

In advancing an arrangement appropriate for the problem, the NAS initiative proposes to place primary reliance on a set of rules that would be established among practicing research scientists who would also be the principal agents of enforcement. The central provision of the BWC -- a categorical prohibition on offensive application of biological agents -- would be promulgated as a legal and professional obligation of all scientists and research workers authorized to deal with the designated pathogens. Anyone so authorized would be obliged to register with an oversight institution and to declare the basic purposes of their research activities. The same institution would record all known strains of the designated pathogens -- information that is particularly important for preparing preventive and therapeutic measures. It would also establish procedures for collaborative reaction to any actual outbreak of the diseases in question. The oversight institution would be established in the first instance by Russia and the United States with the intention of ultimately making it a global arrangement.

Such an arrangement would extend responsibility for compliance with the BWC down to the individual level and would build up a set of basic standards and transparency procedures designed to reinforce and protect this fundamental responsibility. It would aspire eventually to encompass all individuals who handle the designated pathogens and to make any unregistered activity *ipso facto* illegitimate. The oversight organization would be responsible for recording information rather than issuing approval or undertaking direct enforcement, but it would develop guidelines for safe and responsible practice that the participating governments would act to uphold. The scheme might be characterized as organized and transparent self-enforcement.

The principal incentives that the oversight institution would have at its disposal would be positive in character. It would be a principal channel of financing research work on the disease pathogens and also the basic repository of information on strain variations. Access to financing and information would depend on compliance with the institution's basic guidelines. Presumably provisions would have to be made for the institution to initiate remedial action in instances where there is evidence that its guidelines are being violated, but negative enforcement actions -- changing the directing personnel of a research institute, for example, or prosecuting individuals -- would remain the responsibility of the relevant government. In instances where some government appeared to be the source of violation, the oversight institution's standards reflecting general public health interests would provided the basis for the participating governments to organize effective sanctions.

add incentives for "conversion": < legit. funding

CENTRAL ISSUES

There are a number of demanding issues that would have to be resolved if this basic idea were actually to be adopted and implemented. In presenting its report on the question, the NAS committee appointed to undertake the project will attempt to advance reasonable judgments on the following questions:

1) What pathogens require special handling?

Many thousands of human, animal and plant pathogens have been identified, but only a relatively small number of these have the potential to be used as mass casualty agents. Those that do pose this danger share the characteristics that they ~~spread efficiently among~~ can be disseminated artificially to human hosts, have a high rate of infection, are lethal to a high proportion of those infected, and have a relatively rapid progression of disease. The thought is that some 30 to 50 pathogens can be distinguished by these criteria as requiring the special arrangements ~~suggested with~~ contingency provisions made for new ones that might be identified. or disabling classes of

2) Can the public health and national security functions be effectively combined?

In essence a fully developed arrangement would integrate public health and national security functions for the special disease categories. To be effective the oversight institution would have to enlist the cooperation of CDC and USAMRIID in the United States and the corresponding agencies and research institutions in Russia. That in turn would be a significant organizational innovation in both countries, requiring a different conception of the basic problem and more extensive coordination than appears to have been practiced up to this point. The combination of national security and public health functions makes sense if it is accepted that the primary threat is to civilian populations. The historical assignment of BW defense functions to the military implicitly assumed that the primary threat was to military forces.

3) What is an appropriate budget for the oversight activity and from what source would it be provided?

It is presumed at this point that the oversight organization would have a governing board routinely meeting perhaps at quarterly or six month intervals with an executive director and a small permanent staff. In the initiating phase the board would be appointed by the Russian and the United States governments and would in turn appoint the executive director who would hire the staff. The staff would include both American and Russian nationals. There would have to be office locations in both countries. Most of the budget would be expended on research grants carried out by established research institutions in Russia and in the United States. There would have to be provision in the budget for periodic training of teams prepared to react to any disease outbreaks, but presumably any major actual exercise of that sort would have to be financed from the regular operating budgets of the two governments.

In the course of the project the NAS committee expects to develop rough estimates of what an organization of this sort should cost and the main determinant will be the scope of the research effort that ought to be sustained. At the moment it is imagined that the appropriate amount would be on the order of $10 million per year jointly provided by the Russian and United States governments.

5) What is the appropriate sequencing and proportionate burden for developing the organization?

It is important that the oversight organization operate from the start on principles of full reciprocity and that its costs and benefits be equitably shared. As a practical matter, however, it seems probable that during an initial phase the United States would have to provide a disproportionate share of the financing. The final report will suggest a schedule for developing the institution that balances considerations of equity and practicality.

6) How is assurance of compliance to be achieved?

One of the major dilemmas in developing the suggested arrangement is determining the level of confidence in BWC compliance that must be established at each stage in the process. A fully matured arrangement would provide cumulatively improving assurance that the participating governments were not harboring illegitimate activities of any serious significance. There is unlikely to be any feasible means, however, of establishing a very high standard of confidence instantly. Despite that reality, there is a tendency in the American political system and potentially in the Russian one as well for elected officials to insist on unimpeachable assurance as a precondition for systematic collaboration rather than as an eventual result. In particular legislators appropriating financial support will predictably insist on credible provisions for preventing research results and registered information from being diverted to offensive purposes.

The project will attempt to devise appropriate measures of reassurance for this situation and will attempt to suggest a practical schedule for implementing them. At the moment it is imagined that these would rely primarily on agreed transparency rules. Presumably there will have to be some connection between the size and scope of the joint research effort that is undertaken and the completeness and robustness of the transparency rules. The basic objective in this regard is to provide enough confidence at the start to be able to initiate the collaborative process that is expected to provide high confidence over time.