Observations on China's New Biosafety and Biosecurity Framework

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The challenge of creating a regulatory framework in the arena of biosafety and biosecurity—a challenge to which the Chinese have set themselves as several of these essays describe—is to strike a balance between preventing the accidental or deliberate release of dangerous or even deadly biological agents and unduly infringing upon the liberties of researchers who are conducting perfectly legitimate and necessary public health research. Part of the difficulty in creating such a framework may stem from confusion surrounding the concepts of biosafety and biosecurity. Biosafety can simply be defined as the collection of procedures and technologies developed to protect researchers from infecting or affecting themselves with the diseases they are studying, or from accidentally releasing them into the broader population or the environment.

Historically, in the United States, biosafety has been a largely voluntary regulatory framework based on risk assessment recommendations. The U.S. Centers for Disease Control and Prevention, the CDC, regularly updates the manual on which these regulations are based. The World Health Organization also routinely releases updated recommendations on biological safety. Despite heavy reliance on voluntary compliance, this framework has, so far, been enormously effective in the United States. Practically speaking, scientists do not want to become ill or die from their work, and it would damage any institution's public trust and reputation to release a pathogen into the environment. So, for the most part, U.S. laboratories have welcomed and implemented the proposed guidance points for self-regulation.

In contrast, biosecurity has seen its most dramatic regulatory progress in the past ten years, aside from the lack of international action under the umbrella of Biological and Toxin Weapons Convention intercessional discussions. Particular emphasis has been placed on biosecurity following the 2001 anthrax assaults on the United States. Laboratory biosecurity measures aim to prevent the theft or diversion of pathogens for malicious use. The majority of the United States' regulatory efforts have focused on the "guns, gates, and guards" approach, essentially locking up the pathogens and limiting

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access to them, and developing criminal penalties for those who gain or provide unauthorized access or who otherwise violate biosecurity regulations.

In the United States, there is some overlap between these two fields because both are based on risk assessment of particular pathogens. Biosafety provides published guidance to determine how inherently risky it is (to the researcher as well as others in and beyond the laboratory) to study or conduct certain procedures with an organism, as well as what practices should be followed to prevent accidental exposure to the organism. Biosecurity is intended to prevent the deliberate theft, diversion, or intentional release of certain organisms deemed to be highly at risk for potential misuse as biological weapons. All scientists are concerned with biosafety because of their interest in protecting themselves, their colleagues, and their communities; the subset of these scientists who handle pathogens classified as "select agents"— a list of specific organisms judged as posing a high risk to the public if intentionally released—are concerned with biosecurity. Some overlap between the two areas therefore exists in practice, but the regulatory framework for each evolved along different assumptions and norms.

The Chinese framework described in these essays combines the concepts of biosafety and biosecurity much more thoroughly than in the United States. According to the essay authors, the Chinese regulations are drawn from the "best practices" of international biosafety and biosecurity regulations. While there is great conflation of the terms, infractions of the regulations of either type carry approximately the same penalties.

Discussions of biosafety and biosecurity are equally relevant in the context of these essays. Quite a few organisms, even if they are not deliberately weaponized, could cause considerable harm if released into the general population. The field of biosafety is currently undergoing major changes: as reported by *Science* magazine in 2006, total global expenditures on health research and development rose from $30 billion in 1986 to almost $106 billion in 2001, demonstrating the expanding scope of this field. The total expenditure on health research is now even higher than in 2001 because of mega-philanthropy projects (e.g., Gates Foundation) as well as investment by individual nations. With the expansion of public health research, governments and other organizations are increasingly recognizing the importance of biosafety. Another factor driving increasing awareness of the significance of biosafety is the number of emerging

infectious diseases in the world. Outbreaks of these diseases, which may have recently appeared for the first time in human populations or may have reappeared in a form that is difficult to fight with available treatments and public health tools, have proliferated in Asia, particularly Southeast Asia. The countries in that region have a definite stake in increasing the amount of research they do on these emerging or re-emerging diseases, many of which are novel and have no medical remedy.

The outbreak of SARS provides a compelling example of the problem of emerging infectious diseases. Between the first description of the disease in November 2002 and July 2003, there were approximately 8,000 probable cases and just fewer than 800 deaths worldwide. The epidemic cost Asia approximately $30 billion in terms of losses in tourism and business and in other direct costs. However, from August 2003 to November 2004—when the natural course of infection appeared to have burned itself out—there were seventeen confirmed cases of SARS. Of these cases, four appeared to be community-acquired from Guangdong province; a direct source for these infections was never found, but it appeared to be naturally occurring and probably stemmed from exposures at an animal market. Six other cases were laboratory-acquired, including one in Singapore, one in Taiwan, and four in China. One of the laboratory-acquired infections led to seven additional infections and one death. Evidently, in the second year of SARS, the vast majority of SARS cases came from laboratories that were studying the disease. In none of these cases has it been assumed that there was a profound failure of technology or equipment. The problem was that the people who were working with those organisms lacked the training, the resources, or the energy to follow through with good biosafety practices and consequently put themselves and others at risk.

The case of H5N1 avian influenza is equally relevant. The World Health Organization and the Food and Agricultural Organization of the United Nations have tracked outbreaks of H5N1 in poultry and wild birds from 2003 to mid-2007.[2] Not surprisingly, the countries most affected are the ones are most interested in conducting research on the disease, which is now endemic throughout Southeast and East Asia. Currently, H5N1 influenza does not pass easily from person to person, but if a strain

[2] For more information on the World Health Organization's response to avian influenza, including maps showing outbreaks geographically, see: www.who.int/csr/disease/avian_influenza/en/.

appears that is more communicable, the same countries will be collecting specimens and conducting research on them. Biosafety failures involving a highly infectious strain of H5N1 avian influenza similar to those that occurred with SARS would be far more disastrous than the SARS "laboratory escapes." The need for improved training and resources in these countries' biosafety regulations is obvious.

Oversight and regulation of any activity is composed of several layers of regulatory frameworks and implementation. As can be seen with regard to oversight and regulation of biosafety and biosecurity in the United States and elsewhere, the devil is in the details of implementation. One essayist in this collection, Dr. Hu Longfei, makes the observation that by drawing on the best practices of international biosafety and biosecurity recommendations from a lot of countries, China has created "an almost ideal regulatory framework." While it is true that the framework that Dr. Hu and his colleagues describe is very comprehensive, the laws and regulations it comprises must be implemented thoroughly at the national, provincial, and local levels of government. The framework addresses minutely what the regulatory controls and technological demands are and contains penalties for noncompliance. The implementation of such a complex system at multiple levels is a considerable undertaking. On the plus side, China's new regulatory framework also inherently conveys certain norms—the cultural implication that both biosafety and biosecurity are important and worth investment.

What the essays on this framework do not address is what happens at the next level below that of local government. Most of the responsibilities for implementation of these regulations lie with the individual institutions or laboratories, and this creates two problems. The first, as Wang Qian observes in her essay, is that the regulatory framework does not apply to every laboratory. In fact, China's regulations appear to apply to a fairly narrow number of laboratories with a specific definition and government funding. As described here, they apparently do not apply to academic laboratories, to hospitals, and to some commercial facilities; the regulatory framework is therefore limited in its requirements of compliance. The second problem is that it is unclear who will provide the resources and training to implement the regulations and to oversee the laboratories within these institutions. Resource shortfalls are a particular difficulty at the

institutional level, because the responsibility falls on the lead researcher in each laboratory to directly oversee and train his or her staff.

This issue exposes a more general problem: a shortage of experts, which is an observation made by several of the essayists. Worldwide, there is a dearth of biosafety professionals sufficient to meet the growing demand. In the United States, there are not enough trained biosafety professionals to contribute to widespread training in the expanded U.S. biosecurity regulatory requirements, and there are certainly not enough in China to meet the new demands imposed by an enormously complex, brand-new regulatory framework. The number of people who could possibly understand these regulations and implement them at a policy level is probably quite small, but the number of people technically trained to implement them is even smaller. Additionally, most of the global experts in handling highly infectious diseases are in the United States and Europe; they may be barred from easily inviting their Chinese counterparts to their laboratories to observe their practices with specific pathogens and how their regulations are implemented because of the select agent rules and other regulatory obstacles. China must therefore import experts from other countries to train scientists locally. So, the shortage of biosafety professionals and the need to import them will complicate China's efforts to implement its new regulatory framework and improve it subsequently.

Currently, China's regulatory framework is just that—a very well-described, detailed *framework*. Because it applies to biosafety and biosecurity equally, it may well be very powerful, but the proof of its success will be in its implementation at the local level. The potential difficulty in local execution of a centrally designed policy is suggested by a January 2000 National Intelligence Council study that classified China among "countries with less developed health care infrastructures," noted for concentration of epidemiology and health care capacities in the capitals and uneven facilities elsewhere.[3] The SARS crisis emphasized the worrisome public health consequences of China's troubled health care system reforms, and subsequent assessments of health indicators suggest that the Chinese Ministry of Health has experienced considerable obstacles in enforcing government policy decisions at the local

[3] Dr. David F. Gordon, "The Global Infectious Disease Threat and Its Implications for the United States," NIE 99-17D, National Intelligence Council, Washington, D.C., January 2000, http://fas.org/irp/nic/infectious_diseases_paper.html.

level following the massive decentralization of the Chinese health care system, particularly given the funding environment for local hospitals. One observer of China's efforts to implement regulations throughout its health care infrastructure has dubbed this situation a problem of "creative local implementation," implying a lack of implementation at all.

The implementation of the new biosafety and biosecurity regulatory framework at the local level may well pose a similar problem for China, particularly if the framework is applied, as it should be, to the full range of laboratories that work with highly contagious infectious diseases. Without a well-designed plan and resources to ensure effective implementation of regulations and oversight of practices at all levels in China, the advances in biosecurity and biosafety thinking that are described in these essays will, quite frankly, serve no purpose.