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Biotechnological research on the most dangerous pathogens: Challenges for risk governance and safety management

Michael Baram

Boston University Law School, Boston, MA, United States

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ABSTRACT

Biotechnological research on the deadliest pathogens has rapidly grown into a vast enterprise in the United States. With over $50 billion from federal agencies, thousands of projects are conducted at hundreds of university laboratories and other facilities in a national effort to gain the knowledge and methods for preventing the natural occurrence of pathogenic disease and protecting against bioterrorism. This paper describes this enterprise, defines several risk scenarios unrelated to terrorism which threaten lab workers and the public with lethal and contagious pathogenic disease, and evaluates the official policy framework for decision-making with regard to preventing and responding to the risk scenarios. It finds that the framework emphasizes physical security and secrecy to prevent terrorist exploitation of the enterprise, but fails to sufficiently address prevention of lab mishaps, accidental releases, and other incidents during the routine conduct of research which would expose workers and the public to the lethal pathogens. Nor does the framework effectively provide for the emergency response measures needed to prevent an accidental release of the more highly contagious pathogens from spiraling into a local or larger scale disease epidemic. These findings, supported by the growing number of near misses and small-scale incidents and lawsuits, point to major weaknesses in federal oversight and regulation, official disregard for siting criteria, inadequate self-regulation and management of lab safety practices, breakdowns in reporting systems, and obstacles to organizational learning and emergency response created by secrecy and security policies. Recommendations are made regarding these inadequacies of the federal framework and urge application of lessons learned from safety science experience with other hazardous technologies where increasing attention is being given to safety culture initiatives.

1. Introduction

New technologies are often rapidly exploited for their potential benefits before society is sufficiently informed and prepared to govern the risks involved. A prime example at this time is the application of biotechnology in a large scale research enterprise that is focused on the most dangerous disease-causing pathogens known, such as the Marburg and Ebola viruses, Rift Valley and Lassa fevers, and Anthrax.

Proponents of this research enterprise in the US and several European and Asian nations (UPMC, 2007) are those public health leaders and scientists who anticipate that biotechnology will produce the vaccines and therapies needed to defeat these naturally occurring pathogens, and military and national security advocates who believe it will provide them with improved capability to detect and defend against bioterrorism and bio-warfare. In the US, these disparate and powerful interests, evoking both hopes and fears, have converged and secured strong political and financial support, and quickly enlisted academic research institutions and high-tech sectors of industry in the conduct of thousands of research projects on the lethal pathogens at hundreds of laboratories across the nation. (GAO, 2007a).

Because this national research enterprise involves producing samples of the pathogens, shipping them to hundreds of laboratories, storing and handling of the pathogens by researchers, and using the pathogens in experiments which involve infecting a multitude of animals, there are many opportunities for mishaps and accidental exposures within the labs which infect researchers and other workers, and for accidental releases into host communities which endanger the public. Lab mishaps, exposures and infections, and near misses of releases have already occurred because of human error, equipment malfunction, and supervisory negligence (GAO, 2007b; Pearson, 2007; Kaiser, 2007).

In addition, because many of the pathogens are highly contagious, a release (i.e. loss of containment) from a lab can infect members of the local community and, in a worst case scenario, spiral into a devastating epidemic of lethal disease at regional, national or even global levels. Since there are no vaccines or effective medical

E-mail address: mbaram@bu.edu

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therapies for many of the pathogenic diseases, and emergency measures for testing and confinement of exposed populations are problematic, it is not an overstatement to say that accidental release of a highly contagious pathogen could lead to an epidemic on the scale of the Black Death plague of the middle ages and the global influenza pandemic of the 1920s (GAO, 2007b; Pearson, 2007).

From a risk assessment perspective, the combined likelihood, severity and magnitude of the health risks posed by these pathogen research projects far outweighs the health risks posed by technologies which use toxic chemicals, explosives, or radioactive materials. Nevertheless, it is beyond dispute that progress against pathogens would produce great benefits for human health and societal well-being, especially in less-developed nations where many of the pathogens naturally occur, and that being able to defend against bioterrorism has regrettably become a necessity for many countries (NAS, 2004; EU, 2007).

Therefore, the critical challenge is whether progress can be made towards these societal goals without infecting the research workforce and the public with contagious and lethal disease during the conduct of research activities and after their termination. Meeting this challenge requires a coherent national framework for planning and decision-making with several essential features. One is that the framework must encompass plans and decisions regarding the design, siting, operation and decommissioning of all facilities and projects which involve highly contagious and lethal pathogens. A second feature is that the framework must impose the most stringent safety requirements and standards of practice on decision-makers at the macro- and micro-levels; i.e. on the national authorities who approve and regulate the facilities and projects, and the institutions and researchers who manage the facilities and projects, A third feature of the framework is that it must ensure that effective plans for emergency response are available to local authorities for coping with contingencies.

The purpose of this paper is to present a constructive critique of the American framework for planning and decision-making that currently applies to the pathogen research enterprise and to make recommendations for its improvement with regard to several risk scenarios that need immediate attention. The scenarios presented involve the unintentional release of pathogens during routine research activities and the subsequent exposure of lab personnel and the public to infectious disease. Other plausible scenarios of considerable concern, such as intentional release by terrorists or a malevolent researcher, lie beyond the scope of this paper.

For this purpose, the paper discusses the rapid growth of the enterprise, defines the selected risk scenarios, evaluates the current framework in the US for preventing and responding to these risks and its shortcomings, considers the relevance of what has been learned by applying safety science to the management of other hazardous technologies, and recommends several regulatory and management reforms for improving worker safety and public health. In doing so, the paper also discusses growing public discourse and activism against pathogen research; the roles of interest groups and the courts in promoting more sophisticated risk assessment and precautionary decision-making to compensate for regulatory failings; and the difficulties for safety management that arise from the security and secrecy features of the current policy framework and the mind-set of the research sponsors and supervisors.

Many other concerns about the enterprise lie beyond the scope of this paper. One is that the emergency response plans needed to cope with accidental release will involve population controls which require subordination of highly valued civil liberties and individual rights (Bayer and Colgrove, 2008). Another concern is that such research has "dual use" potential in that the knowledge gained for preventing and treating pathogenic disease may also be used to enhance bio-warfare and bioterrorism capabilities. (NSABB, 2007; Pearson, 2007).

2. The pathogen research enterprise

2.1. Challenges

Biomedical researchers and microbiologists have, for decades, sought to understand the pathogenic sources of infectious disease and their pathways of transmission, and to develop the vaccines and medical therapies needed to protect public health. Public agencies, international organizations, and scientific associations have also developed plans to prevent, isolate, contain, and treat disease outbreaks. Over many years and across many nations, these efforts have been joined, have defeated smallpox and polio, and made advances against AIDS, tuberculosis, influenza, acute respiratory diseases, and various water-borne diseases.

However, outbreaks of fatal diseases continue to occur, especially in developing nations, and, without effective vaccines and therapies, can only be dealt with by inadequate medical treatments and quarantine procedures to prevent epidemics. Among these diseases are Marburg, Ebola and Hanta viruses, encephalitis, MonkeyPox, Tularemia, and Rift Valley and Lassa fevers. The challenge of preventing and containing these diseases is considerable, and is now magnified by features of globalization such as increased travel, immigration, and commerce. In recent years, global contagions by SARS and Avian Flu virus have occurred, and caused fear of epidemics on a scale which could rival the bubonic plague of the middle ages and the influenza pandemic of the early twentieth century (WHO, 2005). Thus, activities involving pathogens are considered a major emerging threat on a global scale (Lloyd's, 2008).

Another challenge is posed by the advent of terrorism. Evidence from various sources indicates that terrorists, such as the Al Quaida network, want to use biological weapons to further their causes. Although their technical capability to make and use such weaponry at this time is debatable, there is considerable alarm in many nations that knowledge needed for deploying the most lethal pathogens is becoming available, and if put to such use, would cause widespread panic and harm (NSABB, 2007).

Biotechnology now plays a major role in addressing these challenges. Progress in genomic analysis of pathogens, insect vectors and human beings, and techniques of genetic splicing and other manipulations indicate that biotechnology will facilitate development of effective vaccines and therapies (Klempner et al., 2007). But accompanying these hopes is fear that such accomplishments will have "dual use" potential because the knowledge and skills gained are likely to also be used to create variations of existing pathogens for military purposes, against which the newly achieved vaccines and therapies will be ineffective (RNAAS, 2007; NSABB, 2007; NAS, 2004) In addition, biotechnology has spawned "synthetic biology", a sub-field which aims to create new organisms which do not occur in nature, by using "off the shelf" materials and which has as its first successful outcome, a synthetic reproduction of the dreaded polio virus (Balmer and Martin, 2008). Concern that such research can create new tools for bio-warfare and bioterrorism has motivated government-imposed security and secrecy requirements, a development which is antithetical to democratic systems of risk governance and obstructs the organizational learning needed for effective safety management (Miller, 2004; Kahn 2004).

2.2. Federal programs

For many years, federal agencies which promote public health, agricultural productivity, and military interests have carried out research on dangerous pathogens at government facilities and also funded such research by microbiologists and other scientists in universities and other organizations. Two agencies, the National