Among crimes, the most despicable is treason. Among crimes against humanity, the most despicable is species treason – giving aid to the enemy in the perpetual war between humanity and microbes. Using disease, traitors to humanity could inflict death tolls beyond the great historical scourges and unleash panic of biblical proportions. These perpetrators of disease crucially impart the one quality that microbes lack: they think. The microbes, operating through remarkable processes of trial and error, have never designed a strategic battle plan to resist the onslaught of modern medicine. But their new ally can strategize and find people’s most sensitive vulnerabilities. This ally of disease is as dastardly as can be imagined for this ally is human.

Bio-violence is the infliction of harm by the intentional manipulation of living microorganisms or their natural products for hostile purposes. Worldwide, a most deeply rooted and widely acknowledged normative principle is that it is wrong to intentionally inflict disease. Use of disease is repulsive; it always has been. From the very beginnings of law, there have been prohibitions against inflicting disease against enemies.\(^1\) Unlike other issues of security policy (e.g., nuclear weapons disarmament), there are no legitimate advocates of bio-violence; no nation has a declared bio-weapons program; and no diplomat in recent years has advocated anything other than prohibition of bio-violence capabilities.

Yet, advancing policies to prevent bio-violence is what the international community does worst. Despite the elaboration of normative prohibitions including the Biological Weapons Convention (BWC),\(^2\) various States throughout the 20\(^{\text{th}}\) Century developed capabilities for – and in some cases used -- bio-violence devices.\(^3\) Today, no other threat presents such a stark contrast...
between, on the one hand, severity of harm along with global denunciation but, on the other hand, an absolute failure of leadership to reduce risks.

There is no strategic agenda to guide progress; massive and critical constituencies are disengaged; and there is no capacity to induce States or persons to meet their responsibilities. The BWC is the most vital international instrument relevant to bio-terrorism, but key provisions have uncertain scope and are incomplete with regard to threats of non-State bio-violence; efforts to strengthen the BWC are diplomatically stymied. In view of these conditions, strengthening that normative prohibition is both necessary and insufficient to prevent further bio-violence.

Thus, at the center of global efforts to prevent bio-violence is a black hole sucking in initiatives and emitting nothing. Why? because there is no international authoritative structure – rule of law – that can promote reasonable, even widely-shared initiatives to reduce bio-threats. No global body is authorized to define and enforce policies to secure pathogens, control critical equipment, or detect covert bio-violence preparations. For every other substantial threat to humanity, a designated multilateral body monitors compliance with shared global norms. But confronting all who are concerned about bio-violence is this fundamental and unique condition: international alarms of bio-violence ring nowhere!

Bio-violence is a crime that must be prevented. It should be a crime whether the inflictor is a State or a person, a terrorist or a criminal, or just a lunatic. Law enforcers worldwide should be engaged in interdicting this crime. That’s a complex undertaking with many details, but not one that is beyond human intellect. We can make the world a lot safer, save some children from dying whether by hand of nature or man, and, most intriguing, we can appreciate the role of law in shaping human affairs at this time.

It is time for international legal action to prevent bio-violence.

What Is At Stake

At some point, fanatics will see that conventional attacks just are not doing the trick. Kill a few hundred people, and foreign armies still traverse the world. Leaders in Washington, London, etc. are resolute. To rattle modern civilization, fanatics had better do it the way the deity has done it since the days of pharaoh: inflict a scourge. For them, the taboo against inflicting disease is manifestly irrelevant. Especially for a religious zealot, bio-violence has biblical precedent for wreaking holy wrath on the infidels. The association of pestilence in sacred
texts as forms of divine punishment may abet their plan to provoke an apocalyptic confrontation between the forces of good and evil. Causing collective death and misery may be seen as performing a sacramental reckoning that morally justifies mass murder.

How hard it is to perpetrate bio-violence is in sharp dispute. Making a lethal bio-device is well within many people’s capabilities; the necessary agents and equipment are readily available. Some experts assert that bio-science students could safely prepare an agent, although weaponizing that agent might require greater sophistication. And the risks of a covert laboratory being detected are slim. A single individual can smuggle a bio-device across borders by land, sea, or air and through customs checks. They can be disseminated without drawing an iota of attention. It might be days before release of disease agents produces any symptoms whatsoever, and these symptoms might initially be mistaken for a natural disease. The perpetrator by now may be anywhere. Moreover, dissemination of lethal microbes need not leave traceable markers. No other weapon offers a comparable capacity to inflict catastrophe anonymously.

But the principal characteristic of bio-violence – which is true for only a few biological agents – is contagion. The use of a contagious agent is wholly different than any other type of attack which, regardless of its horror, is confineable in time and space. Any other lethal device inflicts harm where it is used. It’s horrible for the victims, but if you aren’t there, its effects are emotional – grief, empathy, rage, etc.; it does not harm you physically. But a contagious bio-attack somewhere puts everyone at risk everywhere. It could begin against a small group (perhaps at a transport hub); the victims would themselves become extended bio-weapons carrying the disease indiscriminately. With modern transportation networks, an effectively spread highly contagious disease could run amok and expose vulnerabilities around the planet. No other attack offers similar capabilities to spread itself. And the bugs couldn’t care less.

The potential number of victims is unknowable. The Spanish Flu outbreak of 1918 killed upwards of 50 million people in a world with one-third of today’s population and without modern transportation networks, albeit also lacking modern drugs and medical resources. A perpetrator of a bio-attack could be far more artful than nature in disseminating disease around the world. Predictable fatalities are merely hypothetical numbers: whether 5 million or 150 million, the devastation is unlikely to leave survivors with anything like currently existing institutions or prevailing concepts of how to get along on this shared planet.
And finally, there is the factor of mass panic. If there’s a successful bio-attack with an extremely lethal and contagious agent, the very constitution of our civilized order could be unraveled. Bio-violence is, ultimately, about hiding our children. It is about planes flying empty or perhaps not flying at all. It is about people refusing to interact with neighbors for fear of unseen and horrible affliction. It is about disruption of business, entertainment and indeed all facets of modern life. Bio-violence makes everyone in a society potentially vulnerable to our most fundamental terror: the fear of disease.

**Prevention or Vulnerability Reduction**

Although often used as synonyms, the terms *prevention* and *vulnerability reduction* refer to distinct policy sets. Policies to reduce vulnerability improve the potential victim population’s ability to withstand a bio-violence attack. These policies include: creation and distribution of vaccines and antidotes; equipping public health; and installation of early warning surveillance. So-called *bio-defense* programs to promote development of vaccines and early response capabilities also are, broadly stated, examples of vulnerability reduction policies.

The threat of bio-violence would be solved, of course, if vulnerability reduction policies could be broadly effective. Undeniably, implementing effective measures to reduce vulnerability can save lives, and immunizing people against likely bio-violence agents compels attackers to pursue less preferred agents. In specific contexts where an immense threat is highly susceptible to medical counter-measures, it would be the height of folly to not protect people. A clear example here is stockpiling vast quantities of smallpox vaccine and distributing it widely so that it can be quickly pushed where needed, along with training health care workers who must be mobilized at short notice. Precluding a smallpox pandemic by greatly reducing vulnerability makes obvious sense.

The same can be said of mitigation measures to limit the extent and severity of an attack’s consequences. Effective mitigation planning might convince potential bio-attackers to take their malevolent energies in a different direction because pursuing bio-violence will not catastrophically ruffle a community where public health capacities can efficiently contain the damage of an inflicted illness. Or, these measures might divert attackers from simpler and less detectable attack modes to more complicated schemes that more likely could be noticed with careful scrutiny. And the indisputable argument in favor of mitigation measures is that they have
value against natural epidemics; resources invested in public health response capabilities are worthwhile even if a bio-violence never happens.

The problem with vulnerability reduction policies is that the attacker needs to pierce only at the most vulnerable point. If there were only a handful of bio-violence agents and effective immunities or antidotes against each of them, then such measures might suffice. But there are too many; full-spectrum immunization against such myriad threats is not only unrealistic, it would likely kill the people that need protection. Moreover, the pace of emerging bio-science increasingly could enable modestly trained scientists to bio-engineer around even the best defenses, opening ever-vaster prospects of misuse with ever-easier ways to exploit gaps in society’s medical defenses. Given the range of available agents, the agent-specific nature of most defenses, the lengthy time needed to develop new vaccines, and how easily an attacker can achieve surprise, protecting a large population against numerous threat agents is a daunting and hugely expensive undertaking that might easily be eluded. Simply stated, vulnerability reduction strategies are undependable for containing the suffering, loss, and ensuing panic caused by a well-designed disease attack.

In distinction to vulnerability reduction policies that strengthen potential victims’ resistance, prevention policies focus on disabling or stopping the perpetrator. Preventing bio-violence entails raising barriers to acquisition or development of lethal devices and, if those impediments are circumvented, enabling interdiction of wrongful preparations before the attack is executed. Thus, while vulnerability reduction policies are primarily concerns of health care sectors, prevention policies are primarily concerns of law enforcers: police, inspectors, border and customs officials, etc.

Moreover, implementation of prevention policies raises very different implications. Choices about vulnerability reduction policies pretty much come down to resource allocation questions: how much is it worth spending on any particular vaccine development, production, or dissemination capability as well as to train and equip relevant personnel. Policy choices about prevention also entail resource allocation decisions, but there are uniquely huge issues about the role of law enforcement in supervising bio-science as well as about personal rights of privacy. If there were unlimited resources, it would be hard to object to virtually any vulnerability reduction measure; even with unlimited resources, however, there are compelling reasons to think carefully about prevention’s potential costs to scientific and individual freedom.
Yet another critical distinction is that vulnerability reduction measures can be implemented effectively at the national and even the local level -- a national government can promote distribution of vaccines, and local governments can do crisis response training and build reactive capacity. But prevention policies that are less than global are marginally useful at best. Perpetrators sophisticated enough to undertake catastrophic bio-violence are apt to go wherever prevention measures are weakest. If there was ever a problem that transcends the division of the world into almost 200 sovereign nations, it is the threat of bio-violence. Disease has no regard for borders; pathogens don’t carry a passport. Any sizeable bio-attack will have trans-national consequences and demand new modes of cooperation. Even if a bio-catastrophe stays within a single region, the global economic costs are likely to be devastating, and threats from the perpetrator that similar affliction will befall another region – even if wholly false – would hardly be ignorable.

Stated simply, vulnerability reduction policies have substantial promise and are valuable even if bio-violence never occurs. As these policies are resource-intense and will tend to be implemented nationally and locally, each community can and should decide its preferred level of commitment to advancing relevant capabilities. But, outside of more comprehensive prevention policies, vulnerability reduction measures are a Maginot Line. The threat of bio-violence is perhaps the clearest and most unarguable example of why the world should initiate policies for sharing information, advancing joint response modalities, developing multilateral training capacities and command responsibilities, etc. Thus, efforts to prevent bio-violence have the inherent implication of shrinking the planet into an interdependent neighborhood.


Disease and strife are the Achilles Heels of our age; bio-violence is where they intersect. It might be asked why this threat has not already been addressed, why international and national leaders have done such a remarkably poor job in diminishing bio-violence risks, leaving us all virtually naked to a bio-attack from a powerful military, group, or single person. Yes, in the past few years, enormous monetary and scientific resources have been devoted for vaccines and antidotes against the most feared bio-agents. Yet real multilateral progress has been eviscerated by concerns for intrusion into domestic spheres and cries to uphold national sovereignty.
This is definitely not the place to call for a radical re-structuring of the Westphalian system, but it is striking how little has been done to make it hard to be a bio-weaponer and shocking that vast resources have been spent without anything like a global approach that might actually make us safer. It is imperative to see that this global threat compels global policies, and these global policies compel nations to cooperate with less regard to their specific national prerogatives. Indeed, adamant proclamations about the inviolability of State sovereignty, in this context, are recipes for disaster.

A first contributing factor to the policy failure may be termed *fragmentation*. Bio-violence evokes no single discipline or bureaucratic specialization. It cuts across the sciences, law, and politics, across academia, government research, and the private sector, across developed and developing States, and across planners who focus on military prowess and those who focus on public health. The result is not that the issue has too many homes; it is that it has no home at all. For example, in the United States government, there’s no office with authority to coordinate, even at the national level, a broad array of policies to prevent bio-violence. It falls through the bureaucratic labyrinth. On the international level, it’s immensely worse.

A second contributing factor may be termed the *phenomenological quandary*. There is a common misperception that all bio-violence agents are essentially similar. They’re not! Indeed, the category is so diverse that to speak of *bio-agents* as a singular type of weapon is misleading. The term refers to a diverse array of microbes and technology that face widely different production hurdles and that have effects ranging from targeted assassination to humanity-wide cataclysm. Bio-violence is a many-faceted thing that can involve any of numerous bio-agents, technologies, and dissemination systems. In truth, just as there is no single bio-violence device weapon, there is no single assessment of the challenges of making and using them effectively; any single policy approach is inherently flawed. Moreover, to a degree unparalleled by any other potential weapons device, science is opening radically new capabilities for both good or ill. Accordingly, strategies to prevent bio-violence should be many-faceted, capable of selective preventive measures and responses to specific types of attacks as well as sufficiently dynamic to address scientific phenomenon beyond current understanding but rapidly approaching.

A third contributing factor may be termed *mis-prioritization*. Should policies to reduce bio-violence threats be addressed before policies to reduce other strategic threats (e.g., nuclear weapons)? Should bio-violence threats take precedence over natural disease threats or over

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famine and poverty? Should law enforcement resources be devoted to interdiction of bio-violence even if that means diverting their attention away from core functions? Should bio-science research be encouraged in the cause of identifying vaccines against bio-threats or should it be discouraged in the cause of limiting the potential for its dangerous applications? These and a dozen other similar questions of priority have one thing in common: they’re inane, and they stop very real opportunities for progress. There are policy formulations that can successfully integrate these priorities. We need not choose between which priority we like more; we can propound ideas that simultaneously advance multiple agendas.

A fourth and final contributing factor may be termed a poverty of foresight. The one constant of issues related to bio-violence is the awesome rate of change: change in the underlying science, change in the institutional approaches of States and international bodies, and change in global politics. The 2001 anthrax attacks prompted a colossal shift of resources toward developing anthrax vaccines; expert attention to smallpox likewise provoked widespread concern with the paltry stockpiles of smallpox vaccine. Such devotion of resources is not necessarily wrong-headed; the problem is that it’s reactive. If there’s a plague attack tomorrow, the President will announce new programs to stockpile antibiotics against Yersina Pestis. If flu is dangerously manipulated into a terror device, an entirely different set of policy initiatives will ensue. Policies are event driven! But nowhere is there systemic evaluation of bio-violence threats that we face today much less the threats that we might face in only a few years.

Simply stated, historical mis-steps in policies about bio-violence have entwined around the complexities of bio-science which have snarled around the futility of tackling an intrinsically global problem in an anarchic and rapidly changing world. The result is a most convoluted knot that won’t conveniently unravel. The issues here are intricate and embedded in uncertainty, requiring elaborate twists and turns through policies that implicate science, diplomacy, and law enforcement. Unfortunately, bio-violence is something of a wild card in a very high stakes game, with humanity’s future at stake. That said, the inherent intricacy of policies to prevent bio-violence can bring into focus global policy vistas, with extraordinary implications.

Notably, in December 2006, the Biological Weapons Convention Sixth Review Conference (BWC RevCon) will convene in Geneva. On this much, there is global consensus: the RevCon will signify nothing. Despite a growing urgency over bio-violence threats and the prevailing concurrence that the BWC is the only multilateral instrument even remotely relevant
to these threats, the attending diplomats might satisfy themselves with bland platitudes and an unproductive workplan until the Seventh Review Conference in 2011; more likely, they won’t accomplish even that much. As they fiddle, we can only hope that bio-violence remains a hypothetical threat.

Imagine, however, an international forum where leaders responsibly confront the challenges of preventing bio-violence. What should they do?

This essay sets forth a framework strategy for preventing bio-violence that the international community should advance through law. In brief, a bio-violence prevention strategy should comprise three categories of policies – discussed in Sections I - III: (1) policies to deny potential perpetrators the agents and equipment that might facilitate their crimes; (2) policies to strengthen law enforcers’ capabilities to detect and interdict covert bio-violence preparations; and (3) policies to oversee the advance of bio-science, including bio-defense programs. Over-arching this strategy is a set of larger issues discussed in Section IV: how to globally govern implementation of and compliance with all these prevention requirements so as to integrate these policies into an inclusive global covenant for combating epidemic disease, whether natural or intentionally-inflicted. Section V assimilates all these bio-violence policies into a set of principles, obligations, and recommendations.

I. DENIAL POLICIES

It should be difficult to gain wrongful access to refined pathogens, sophisticated bio-equipment, and advanced bio-laboratories. The proposition seems obvious albeit imperfect. States and sophisticated criminals or terrorists with extensive resources might develop natural pathogens, and a lot of bio-equipment is available on retail markets. Denying access to bio-laboratories or their contents are not likely to stop low-scale bio-violence involving a common disease agent that is disseminated with little technology, e.g. spreading salmonella on restaurant salad bars. At the opposite end of the bio-violence spectrum, national bio-weapons programs are not likely to be deterred by denial policies. If an affluent State wants to operate a covert bio-weapons program and is willing to bear the costs and potential political opprobrium for explicitly violating global norms, denial measures probably won’t, by themselves, have much impact.

It is the vast range of threats in between – from State-sponsored bio-terror programs to independently-organized criminal enterprises – that are most likely calamitous and that could be
complicated by worldwide implementation of denial policies which make it harder for some perpetrators to undertake some preparations. Of course, just because denial policies are not perfectly effective, they are not therefore worthless.

The essence of these policies is to require that any entity or facility that is working with potentially weaponizeable bio-agents be registered, and that registration should be manifest to international and national law enforcers. Transfer of weapons-capable pathogens should be limited to registered entities; all legitimate transfers should be reported with the name and location of both the transferor and the transferee. Conversely, it should be illegal to sell or distribute certain pathogens to an entity that has not subjected itself to registration, and any unregistered entity found to possess controlled pathogens would be presumptively in non-compliance, without regard to whether evidence can be produced as to that entity's malevolence.

Crucially, these denial policies must be directed at misuses of biology and place only minimal burdens on legitimate science. Their costs must be weighed against their limited benefits. More generally, bio-scientists are concerned that legal monitoring and enforcement of denial policies might compel police to interfere with their work or, worse, insinuate that their work is linked with bio-violence. Perhaps no discipline has made (and continues to make) such profound contributions to humanity as bio-science. Many bio-scientists believe that this progress is directly correlated to minimal governmental intrusion and constraint; law enforcement could stifle life-saving advances.

A degree of anarchy has always characterized the pursuit of bio-science which, at least until recently, could be conducted with minimal resources. Bio-scientists trace their art to Mendel whose breakthrough discoveries happened in his garden. Moreover, bio-science has immediate and direct entrepreneurial implications for the pharmaceutical sector – a sector which, to put it mildly, has issues with legal supervision. And the bio-science/pharmaceutical sectors are crucial allies in efforts to prevent bio-violence. These sectors must undertake research on pathogenicity and virology, produce vaccines and antidotes and instruct first responders on their use, and join with other disciplines to create sensing instruments to assist law enforcement. It would be reckless indeed to view bio-science as dangerous or bio-scientists as suspects for potential bio-violence. More broadly, it’s just patently ridiculous to think that there’s widespread interest among bio-scientists to engage in bio-violence.
Yet, implementing denial policies serves three important objectives. Most important, various bio-attack scenarios could be significantly eased by access to specific agents, bio-laboratories and other advanced capabilities. Implementing denial policies can complicate these scenarios. Second, these policies define a common set of norms and regulatory practices, compliance with which is evidence that purportedly legitimate endeavors are genuine. An elaborate set of best practices encourages worldwide commitment to uniform security measures. And those best practices provide useful criteria to accurately distinguish legitimate bio-scientists from perpetrators of bio-violence. Notably, these policies to complicate bio-violence are standard operating procedure in many nations having sophisticated bio-science sectors. Third, assessing compliance with elaborate denial policies generates copious data that heightens understanding of what legitimate entities are doing and, derivatively, what non-complying entities are doing. Cumulatively, this data can help analysts detect suspicious behavior.

Therefore, the science/commercial/research sector should embrace denial policies as the price of living in a dangerous world. Just as it would be reckless to advocate controls on bio-science that do not effectively reduce bio-violence risks, it would be cavalier to ignore the unfortunate but non-trivial potential that a few bio-scientists could, if wrongfully motivated, wreak disaster out of all proportion to their numbers or resources.

A final consideration here is that an actual bio-attack will inevitably provoke calls for draconian measures to oversee bio-science. That was the immediate reaction to the anthrax attacks of late 2001. If there is any evidence of bio-science involvement in an attack, even inadvertently, the clamor for controls is likely to be deafening. If bio-scientists are truly concerned that, in the name of preventing bio-crimes, law enforcers will interfere with their work and falsely characterize their possession of pathogens and critical equipment, it would be tactically wise to develop reasonable supervisory mechanisms now, before there is an attack, rather than attempt to fend off any oversight whatsoever until a nightmare scenario unfolds.

**Pathogen Controls**

Access to laboratory specimens of readily weaponizeable pathogens should be controlled. If bio-violence perpetrators can’t get lab specimens, they would have to gather natural bio-agents that must be refined, raising technical challenges as well as the chances of detection. But no one knows where all such specimens might be. The ignorance is compounded by the rapid
worldwide proliferation of bio-research and pharmaceutical sectors. In the past, there was a prevailing belief that only advanced laboratories in scientifically-advanced nations with rigorous oversight systems had dangerous pathogens, but the logic of that belief is withering rapidly.

There are many disease agents; some far more weaponizeable, contagious, or lethal than others. A hierarchical list would apply the most rigorous security requirements to agents that are most relevant to bio-violence.\(^5\) Smallpox, anthrax, and plague would be on anyone’s list; other viral agents (\(e.g.,\) ebola), bacteria (\(e.g.,\) tularemia), and toxins (\(e.g.,\) botulism) are also likely consensus items. To evaluate these agents, several questions need to be addressed. Should the list be broadly inclusive or limited to the most dangerous pathogens? Should it include lethal strains that kill slowly such as multiple-drug resistant tuberculosis? Moreover, scientists regularly find new disease agents, and the prospect of genetic manipulation increases that potential. What about the Spanish Flu genome or Avian Flu samples? Should the lists consider virulence factors and toxin genes that might be transferred by genetic engineering to transform a benign microbe into a pathogenic strain or to enhance the virulence of an existing pathogen? Also, should the lists specify agents at the level of strains, sub-strains, or unique identifiers (for example, DNA markers) to permit forensic analysis and tracing?

The pivotal question here is not so much which pathogens fall on which lists – a determination that would quickly be passe. Instead, ask who decides. Today, the crucial failing is not that a list fails to consider a particular pathogen or that some pathogen is listed incorrectly. The crucial failing is that, at least as to human pathogens, no international body makes authoritative decisions. The WHO does not provide lists of violence-relevant bio-agents.\(^6\) Each Member State must identify the agents that it believes pose a threat worthy of preventive and responsive measures.\(^7\) The Animal Health Organization (Office des Epizooties, OIE) has done better with regard to animal pathogens, recently revamping its *world animal health information system* to include a single list of all animal diseases, both terrestrial and aquatic, whose occurrence Member States must report immediately to the OIE.\(^8\)

Flexibility and even some disparity as to agents of concern are expected. According to the WHO, “[A]ppraisals and priorities will certainly differ from country to country, but … prudent Member States will have at least some organization and some plan in place to deal with deliberate releases of biological and chemical weapons.”\(^9\) But this logic is highly problematic: if each State defines its own list of violence-relevant pathogens, then there is no meaningful list
whatsoever, especially in view of the globalization of bio-science where specimens can be readily transferred. How can pathogen security measures proceed without global efforts to assemble schedules of dangerous agents?

Establishing lists of dangerous pathogens is only the first step. These lists should be linked to standards that govern how pathogens are to be handled, marked and stored. Among various documents, the WHO has promulgated guidelines for safe handling of specimens within a lab, avoiding dispersal of infectious agents, proper use of laboratory equipment, etc. As these laboratory techniques and standards are aimed at a wide variety of laboratory activity dealing with pathogens, they do not provide particularized standards for specific pathogens.

At minimum, therefore, an international body (presumably WHO for human pathogens and OIE for animal pathogens) should define a list of pathogens of concern for bio-violence with prescribed procedures for quickly adding newly discovered or created pathogens pursuant to explicit criteria. Guidelines for their secure handling and storage should be binding in the sense that every State should be required to implement those guidelines into their national regulatory measures applicable to bio-science. More controversial is whether there should be uniform standards for marking strains of listed pathogens that designate their locations.

It is insufficient, however, to promulgate lists and guidelines, even if they are binding. Proper record-keeping is absolutely essential to identify and track the location of dangerous pathogens. There are records of declared culture collections, but it is absurd to think that these records are anything near complete. The good news here is that the World Federation for Culture Collections (WFCC) has established guidelines for operating microorganism culture collections. The bad news is that the WFCC is a voluntary organization – a club – of like-minded, well-meaning bio-science institutions. It makes no pretense of governing non-member activities. The problem, of course, is that bio-violence perpetrators are unlikely to join the WFCC; its guidelines are not very helpful in finding or stopping them.

There should be a binding obligation on all States to identify locations where refined specimens of violence-usable pathogens exist and to provide this data to an international body (perhaps again WHO and OIE or perhaps WFCC). If pathogens are marked, these markers should similarly be reported and recorded. And, if pathogens are transferred, this international database should track and maintain oversight of this movement.
Laboratory Controls

Making a bio-violence device is not an effortless task of amassing quantities of a dangerous pathogen. Except for smallpox and certain agro-infections, other less contagious or lethal pathogens must be precisely disseminated to be catastrophic. Preparing pathogens for dissemination poses substantial technical hurdles, but laboratories have pure disease strains with requisite attributes for mass lethality that can more readily be violently used. Moreover, even a pure strain must be dried, milled to a size that the human body can readily absorb, and, typically, aerosolized for dissemination. These tasks are easier with sophisticated equipment found in bio-laboratories. Most ominously, potential perpetrators can, at laboratories, take advantage of new bio-science advances to experimentally modify pathogens into variants that are more lethal or less susceptible to vaccine defenses, greatly enhancing their weapons potential.

Bio-laboratories should be safeguarded to foil criminal activity, including measures to augment physical security and containment. This should be straightforward. Both the WHO and the OIE provide elaborate guidelines for laboratory safety. The *WHO Laboratory Biosafety Manual* (Manual) addresses organization, equipment, personnel, and training in Biosafety Level 1-4 laboratories.\(^\text{14}\) It encourages States to prepare codes of practice for safely handling pathogens in laboratories and emphasizes the need to assess risks of activities involving new protocols or pathogens. The Good Laboratory Practice (GLP) Handbook (2001)\(^\text{15}\) was produced by a Scientific Working Group (SWG) on GLP issues, convened by the UNDP, World Bank, and WHO: Special Programme for Research and Training in Tropical Diseases (TDR). The OIE has manuals that specify laboratory procedures which reflect the *WHO Laboratory Biosafety Manual*’s requirements. Also relevant are WHO and OIE reference and collaborating facilities -- “centres” of expertise that propound standards within an international collaborative network.\(^\text{16}\)

Various smaller and more targeted organizations have made considerable strides in promoting laboratory guidelines. The ISO has issued standards for laboratory operations primarily pertaining to testing apparatus and information technology. The IFBLS provides a forum for bio-scientists to train and exchange information and is broadly interactive with various national and international organizations. Integrating IFBLS methodologies into a broader global
effort could offer real benefits. The IFBLS does not accredit facilities, but it is linked with regional organizations that have that authority. The Global Health Security Action Group (GHSAG) -- formed after the 2001 anthrax attacks of the health ministers of the G-7 nations plus Mexico -- has the objective “to improve linkages among laboratories, including Level Four laboratories, in those countries which have them.”

However, all these guidelines are not binding. There is no way to know where are bio-laboratories that do not accept them nor any way to know if guidelines are everywhere obeyed. Nor is there any systematic information about bio-scientists whose unique capabilities might be relevant to bio-violence. There is not even a database of experts who are or have been working with controlled pathogens. Surveillance of the pharmaceutical, food, and environmental sectors is comparatively thorough, but there are no systematic standards, record-keeping, or data analyses for those sectors that would enable detection of wrongful conduct.

Accordingly, bio-laboratories and other facilities (excluding clinical laboratories) that possess listed pathogens should be identified and registered nationally and internationally. Registration must be contingent upon compliance with uniform standards which ensure that sufficient mechanisms are in place for safe operation including barriers to diversion as well as identification of persons who pose potential risks. WHO and OIE guidelines for laboratory biosafety and biosecurity, including personnel access restrictions and record keeping requirements, should be legally binding for all registered bio-laboratories. Registration is also crucial for the law enforcement policies discussed below: properly registered activities are presumed to be legitimate and their possession of listed pathogens is therefore not a basis of suspicion; by negative implication, anyone found to have listed pathogens without proper registration is culpable without further evidence of malevolent intent.

Increasing laboratory security, therefore, tends to signify some marginal tightening of these mechanisms, harmonizing requirements among nations, and extending relevant obligations throughout the world. There need to be harmonized guidelines to identify and prioritize a laboratory’s assets and identify who might attempt to divert or steal those assets. Security management at a facility should create a list of scenarios that are both possible and likely and that involve various levels of capacity to cause an incident of national or international significance. These scenarios should be evaluated based on probability and capacity to cause a major security threat. Improved security should be aimed at the most likely threats that have the
most capacity to cause harm; contingency plans should also be based on the particular likelihood of a scenario actually occurring. Security management can then determine the relative risks that a facility might face and distribute resources for safeguards accordingly.

Dealing with outside threats entails establishing physical barriers like guards, gates, closed circuit cameras, and electronic access codes or biometric security devices such as fingerprint or retinal locks; data and IT system security; security policies for personnel; policies for accessing select agent areas; specimen accountability; receipt of select agents into the laboratory; transfer or shipping of select agents from the laboratory; emergency response plans; and reporting of incidents, injuries, and [security] breaches.” Internal security measures must be implemented, e.g. not allowing scientists to work alone with especially dangerous pathogens, and security screenings upon exiting a facility to ensure no materials are illicitly removed.

Advanced bio-laboratory equipment that is critical to effective weaponization (DNA sequencers, aerosolizers, etc.) is essentially ubiquitous and therefore a registration process for such equipment would strain credulity. A more limited but easy to implement policy would be to tag such equipment with positioning devices that reveal its location. For legitimate science, the tagged device would have negligible implications, but it would enable law enforcers to track equipment that is operated outside of authorized facilities and to control the transfer of requisite materials and technologies. Databases that record the location of such equipment could usefully contribute to understanding where threats of bio-violence might emerge and thus could be a deterrent to perpetrators who could not be sure if their use of that equipment might reveal the location of their covert preparations.

Persons that have knowledge that is uniquely vital to dangerous uses of bio-science should be trained and credentialed; access should be restricted to anyone else. The purpose of the licensing would be to ensure that the affected individuals are technically qualified (either by virtue of an academic degree or on the job experience), have undertaken biosecurity training (and thus have been sensitized to the dual-use potential of their work and educated about both national and international oversight rules), and have nothing in their background (such as a past biosafety violations) that would make it inappropriate for them to conduct consequential research.
Transport Supervision

It is essential to prevent transfers of pathogens and sophisticated bio-equipment to illegitimate recipients or wrongful diversions while in transit to legitimate recipients. The traffic in these items must be supervised to ensure that unauthorized persons do not subvert legal constraints either by asking for/or purchasing them or by stealing them while outside of a secure facility. To accomplish this calls for a three-dimensional integrated system including standards for and mechanisms to gather information about: (1) labeling and packaging of pathogens and equipment, (2) customs security, and (3) port and vessel security. The good news is that such mechanisms exist; the bad news is that they have evolved separately and only recently has integration emerged as a priority.

Maintaining the security of pathogens and equipment in transport requires that proper records be kept of items as they pass from one point to another and from one person to another. A manifest system should track the movement of pathogens from their original source, through domestic and perhaps trans-national carriers, to their final destination -- that information should also be entered in a database. If pathogens need to be moved, international standards should apply to their packaging and mode of shipment. Carriage of pathogens should be regulated; carriers should be monitored for compliance with handling and storage guidelines. So that transporters know which packages need special handling, uniform labeling of pathogens and equipment in transport is essential. But because containers that hold dangerous items might be mislabeled, the contents of containers should be verified at the point of packaging.

However, a package might appear to be properly labeled and packaged and records might appear to be appropriate, but due to negligence or malice, the container might contain items that are inconsistent with those labels and records. At key points therefore – typically customs and border checks – items need to be checked to see if they are actually what the label says they are. Increasingly, due to the fact that the sheer volume of items in commerce precludes customs checks of even a tiny fraction of containers, it is necessary to verify the contents of containers at the point of packaging. Pathogens are almost impossible to detect using the instruments that can detect many nuclear, radiological and chemical sources. They also can be transported in a variety of containers, including as packets within the bodies of living persons or as virulent infections within the bodies of living suicide-terrorists disguised simply as tourist-travelers.
A related risk is that packages might be tampered with --they might be correctly packaged but altered or replaced along the way. The likelihood of such tampering is highest when the items are loaded for transport or at connection points along the way, i.e. ports. To minimize that risk, port security capabilities should be strengthened and integrated with customs security and container safety so as to focus more broadly on a facility or area than a particular item. Closely related are security capabilities that focus on the vessel (ship or plane) to ensure that only objects that are legitimate and safe get loaded. An unfortunate complexity here is that relevant ports and the vessels are overseen by a disparate array of authorities – local, national, and multinational. The confusion and legal contradictions among these authorities undermines effective implementation of security measures.

**The Challenge of Compliance**

National implementation of denial policies entails establishing a system to register bio-science entities within the scope of national jurisdiction and providing strict penalties for its evasion. To do this effectively requires official supervisory bodies comprised of bio-science experts and linked to complementary oversight bodies responsible for advancing public health and scientific progress. While technical requirements should be specified at the international level in order that such requirements be globally harmonized, national legislation should incorporate binding international requirements into the national system – a well-understood process. Only slightly more complex is establishing linkages between State organs that have some relevant responsibilities and their counter-parts in other States as well as pertinent international organizations.

It is important that legislation make compliance with the registration system reasonably simple and efficient. All potentially relevant entities -- researchers, companies, academic institutions – should be faced with clear criteria as to what activities justify participation in the system and what activities might need to be supervised. Key here is to implement denial policies in conjunction with information management and reporting systems. It should be easy and non-burdensome for entities that are not handling certain rare pathogens nor engaging in certain rare research to comply with system requirements. Accordingly, penalties for a system participant who innocently violates a requirement should be far lower than for an entity who fails to seek registration – the goal is to encourage all legitimate entities to join the system and not be deterred by the worry that a minor infraction will incur massive legal consequences. By contrast,
penalties should be severe for entities found to engage covertly in trans-national conspiracies that might have bio-violence implications.

The greatest challenge is not establishing criteria for bio-entities to satisfy – as mentioned, such criteria should be established at the international level. Nor does setting up the system domestically and enacting penalties for its evasion pose the greatest challenge. The greatest challenge is to be able to retrieve sufficient information about entities’ activities so as to make determinations about compliance. Specifying requirements whether internationally or nationally and telling the bio-science community what to do is straightforward; assessing whether participating entities are observing those requirements and encouraging them to do so is more difficult; but most complex is uncovering entities that are intentionally evading oversight (i.e., outlaws). The challenge is not how to regulate the States and persons who agree to abide by legitimately promulgated standards; it is how to know who has chosen to not comply and how to bring them into line or punish them if their noncompliance is deliberate. Simply stated, this is why implementation of denial policies must be integrated with policies to strengthen law enforcement.

There is a substantial question of State compliance and State responsibility – is a particular State meeting its obligations and, if not, is it responsible for subsequent harm. Yet, as to denial policies, the initial judgment of State compliance is straightforward: has it enacted legislation that establishes comprehensive oversight systems for preventing bio-violence. If so, there remains a question of enforcement, but at least the foundation will be set. If not, then an issue of State compliance necessarily arises.\textsuperscript{23} It must be known whether each State is implementing standards into its domestic legal framework and whether each entity, private or public, is in fact meeting those standards.

II. \textbf{LAW ENFORCEMENT DETECTION AND INTERDICTION OF BIO-VIOLENCE}

Denial policies are not foolproof of course. Effective implementation of these policies deprives bio-violence perpetrators of some of the easier and perhaps most effective routes to carrying out their malevolent plans. But it would be sheer folly to assume that because these routes are complicated therefore bio-violence is completely prevented. Risks remain, albeit marginally lower than if denial policies are not implemented.
To be passably effective, denial policies must be wedded to detection and interdiction policies. Indeed, properly designed denial policies should improve law enforcement capabilities to prevent bio-violence. For example, registration of facilities in possession of listed pathogens means that if a law enforcer discovers an unregistered possessor of such pathogens, that possession would be illegal without further evidence of hostile intent. Moreover, denial policies will enable information gathering that can support detection of covert plans.

Law enforcement around the world has potent crime-fighting capabilities. As the dangers associated with bio-violence become more dire, law enforcement’s capabilities warrant greater consideration. Law enforcers must supervise bio-security measures, detect unlicensed activities that might constitute bio-crime preparations, interdict illicit efforts to use territory to trans-ship pathogens, gather and analyze data for purposes of expanded surveillance, apprehend perpetrators, and mitigate the consequences of a bio-attack and restore order if denial efforts fail.

While law enforcers bear these responsibilities in every State, only in some States are they assisted by networks of professional associations, public health systems, and emergency responders. Unfortunately, in the vast majority of States -- from where bio-crimes may be more likely to emerge -- law enforcers undertake these responsibilities essentially alone. This is especially significant because execution of bio-violence prevention responsibilities demands unique capabilities. There are challenges of knowing how to detect pathogens that are essentially invisible and are inherently dual-use. Law enforcers should have some familiarity with bio-science as well as the operations of research laboratories and pharmaceutical facilities.

These concerns about law enforcement capabilities are severely magnified by three profound problems with detecting and interdicting covert bio-violence preparations: (1) the lack of legal authorization, in most States, for law enforcers to take necessary action; (2) the risk of law enforcers interfering with legitimate bio-science activities by failing to clearly distinguish those activities from bio-crimes; and (3) the inherent challenge of detecting activities before those activities are manifest as a bio-attack.

**Law Enforcement Authorization**

To conduct bio-violence prevention functions, law enforcers need express authorization; without authorization, law enforcers may not legitimately act. But if some States do not clearly deem specific behavior as a crime, if national laws are not harmonized, then dual criminality
may not be sustained – a problem that is especially pronounced in States where proliferation and terrorism are more likely. In that event, international cooperation to gather evidence, conduct investigations, immobilize evidence or proceeds of a crime, prosecute or extradite perpetrators, and produce evidence and witnesses for trial cannot operate effectively.

That States must criminalize bio-violence is highlighted both by the Biological Weapons Convention and by recent action of the United Nations Security Council. Article IV of the BWC requires States Parties to implement measures to extend Article 1’s prohibitions to persons or entities within their jurisdiction – in other words, to make it illegal for anyone to do what would be illegal for a State to do. United Nations Security Council Resolution (UNSCR) 1540 requires all States to adopt and enforce appropriate laws to prohibit development, etc. of WMD, including bio-weapons. Although similar to BWC Article IV, it is paragraph 3 of UNSCR 1540 that adds a new dimension. Each State must:

“[T]ake and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials” These controls include: (a) measures to account for and secure such items; (b) effective physical protection measures; (c) effective border controls and law enforcement efforts; and (d) effective national export and trans-shipment controls over such items.

And, in contrast to the BWC which wholly lacks any institutional oversight of State compliance, UNSCR 1540 establishes a committee to receive reports from States on “steps they have taken or intend to take to implement this resolution” and to report to the Security Council.

Despite these international mandates, most States have not legally proscribed accumulation of bio-agents or critical equipment, no domestic authority is mandated to supervise access to such materials or equipment, and neither domestic law nor international law is violated by the trans-national transfer of such items. Accordingly, in most nations, production or transfer of deadly bio-agents is not a criminal act; there is no legal authority to investigate private biological weapons activities; nor is there any legal way to deprive private groups access to whatever they might need to carry out their plans. Indeed, weaponization of pathogens by terrorists is not a national crime under the laws of all but a handful of nations and, in most nations, no law authorizes law enforcers to detect or interdict preparation of bio-weapons. And, not surprisingly, even if such law enforcement activity were authorized, most States lack capability to carry out detection and interdiction obligations.
Thus, States should criminalize bio-violence activities, attach strict penalties, and establish modalities to detect and interdict illegal behavior. Obviously, use of any bio-agent for hostile purposes should be an offense. It will be necessary also to reach preparatory steps that can overlap innocent behavior or even legitimate scientific inquiry. For example, criminal prohibitions should apply to preparing pathogens for dissemination, construction of a illicit facility for weaponizing bio-agents, diverting bio-agents from a facility, transferring agents or relevant equipment to anyone who misuses them, or tampering with any facility or package containing bio-agents in order to cause their release. No exception should be allowed regardless of the motive for that activity.

Criminal prohibitions should apply if behavior is done for *hostile purposes*, not to activity that is truly inadvertent. For example, a person might tamper with a facility and thereby cause the release of bio-agents but not intend any harm nor to advance a hostile purpose. “Hostile purpose” may be defined to mean intentionally causing serious harm to humans or widespread damage to non-human life or to the environment. Of course, persons might transfer bio-agents or construct laboratories without coming within the scope of the prohibition. Such person may violate the prohibition only if it can be established that the activity is performed in order to cause the specified harm. The requirement of “intention” is to preclude application of the prohibition to activity which is not meant to cause the ensuing harm.

The scope of legal jurisdiction over such crimes should broadly reach the behavior of legal entities (e.g. corporations) and enable prosecution of participants in trans-national conspiracies. States should exercise jurisdiction as broadly as their national law allows. It is crucial, moreover, to require law enforcement cooperation so as to enable each State’s law enforcers to work jointly with their counterparts in other States by sharing information, conducting investigations, and prosecuting apprehended terrorists. States must either extradite or prosecute offenders within their jurisdiction. This requirement obligates the State where the offender takes refuge to take active measures to apprehend the alleged offender.

**The Challenge of Criminalizing Bio-Violence Preparations**

A most gnarlish implication of criminalizing misuse of pathogens is the risk of ensnaring legitimate bio-scientists whose unrestricted exploration and experimentation is enormously beneficial. Thus, to prevent bio-violence, it is imperative to distinguish wrongful preparations
from legitimate science, pharmaceutical production, or even mere flights of imagination. There is a real quandary here. In retrospect after an attack, assigning criminal responsibility to the perpetrator is simple, but that is meaningless from a prevention perspective. Making such distinction before an attack, however, is more problematic. Indeed, the term “bio-criminalization” has provoked some concerns among scientists that police will barge into legitimate labs and haul off scientists for interrogation. The concern is understandable. Law enforcers must make judgments before lethal capabilities are put to harmful use, and, undeniably, many bio-scientists have such lethal capabilities at their fingertip. Today, law enforcers must make distinctions wholly without criteria.

In short, pre-use interdiction is complicated by the fact that capabilities to make biological weapons are virtually ubiquitous and are interwoven with legitimate scientific pursuits. If working with pathogens – refining them into pure strains, culturing or manipulating them into uniform shape and density, and even studying their processes of lethality – is illegal, then hundreds of bio-scientists will face legal inquiry and perhaps worse. If having equipment and knowledge with which bio-violence agents could be prepared, then thousands of bio-scientists including high school biology teachers might be prosecuted. Obviously, this would not serve any beneficial purpose.

Ascribing the status of criminality to advance preparations for actual use of deadly agents raises the risk of snaring legitimate, even compelling, activities within the prohibition; overbroad attributions of criminality could stifle life-saving and economically valuable progress. Of course, States have a right to produce, develop, etc. biological agents for protective and prophylactic purposes, and researchers and pharmaceutical companies have a recognized right to conduct legitimate activities involving pathogens. Yet, from the perspective of actually implementing laws to prevent wrongful uses of bio-science and of instructing law enforcers to investigate capabilities that could be misused, there is little in the science itself that readily distinguishes legitimate scientific activity from preparations to commit a heinous crime.

This is the so-called “dual-use” dilemma. The same materials, equipment, and techniques that are necessary to make bio-weapons are readily available in connection with all sorts of legitimate applications. The dual-use nature of biotechnology means that materials, equipment, skills, and facilities designed for peaceful endeavors can also be exploited for hostile
purposes. These resources are widely available on the open market and are highly sought by countries interested in economic development and by persons seeking to develop biotechnology.

The remarkably simple solution derives from the proposition any person or facility that is working with potentially weaponizeable bio-agents should be registered. As argued above, national penal legislation should target pre-attack preparations for bio-violence by providing that receiving, supplying, or smuggling weapons precursors, critical materials, or critical equipment is presumptively criminal, unless that activity is declared. Registration serves not only to identify facilities or persons that are legitimately working with lethal pathogens; registration also enables law enforcers to oversee that those facilities and persons are themselves complying with reasonable measures to secure their pathogens, equipment, and other potentially weapons-relevant items from diversion. There is, therefore, a fundamental connection between the regulatory requirements discussed in connection with denial policies and the law enforcement policies at issue here. Importantly, this policy intersection must respect the objective of decreasing the risk of an attack by persons who have no regard for law, not to harass persons who in the pursuit of legitimate bio-science research pose no direct threat whatsoever.

**Pre-Attack Detection and Investigation**

To prevent catastrophic bio-violence, it is imperative to detect illegal preparations early. The challenge here is how to know the unknown -- how to detect covert behavior. In other law enforcement contexts, the condition precedent of an investigation is an actual crime -- only when there is manifest evidence that a law has been broken will law enforcers begin to collect information, and the leads for that effort should derive directly or by implication from the crime itself. As a rule, law enforcers do not investigate everyone who has a kitchen knife although it is true that a knife can be a murder weapon. Having the *capability* to commit a crime is not legally significant unless there is other evidence of malevolence or, again, unless the crime has in fact happened. Thus, it is insufficient to suggest that because somewhere, someone in a broad community has capacity to commit a crime therefore law enforcers should be able to investigate anyone who might have criminal intent. Society awaits the crime before authorizing an inquiry.

But bio-violence threatens civilization-unsettling consequences. This is not typical crime. Instead of inflicting dire harm on an individual or small group, a bio-violence perpetrator
could inflict a qualitative leap in devastation. It is incumbent, therefore, to consider how to identify those persons as early as possible, hopefully before their plans materialize.\textsuperscript{27}

Relevant answers may be usefully discussed under the rubric of \textit{expanded surveillance} which aims to identify anomalous conduct that suggest a need for more information. This entails gathering vast and diverse information as to where bio-research and related activities occur and linking that information with data about criminal networks and smuggling operations from police and customs files. Identification of an anomaly by sophisticated analysis of database information should provoke follow-on inquiry, either by requesting clarification from a relevant State, by assigning a “task force” to gather more facts, or by authorizing an investigation.

Thus, \textit{expanded surveillance} necessarily connotes an elaborate system to gather information from wholly diverse sources, analyze that information through complex and integrated databases, and clarify or investigate anomalies. It will be crucial to know how gaining relevant information can be systematically accomplished without violating privacy or confidentiality rights. Advanced data mining techniques are designed for that purpose.\textsuperscript{28} Thus, it is somewhat ironic that as technological leaps (\textit{e.g.} dangerous biological research) are raising threats to the body politic, other technological leaps (\textit{e.g.} information analysis) are increasingly offering capabilities to prevent those threats.\textsuperscript{29}

The key to expanded surveillance is a ready capability to correlate various types of information from disparate sources across bureaucratic or professional spheres. The ability to identify related information in separate databases or investigations potentially gives law enforcement agencies a more complete informational base from which to draw conclusions and enables information to be evaluated in varied formats so as to shed light on terrorist or criminal activity.\textsuperscript{30} Law enforcers frequently gather information regarding patterns of criminal activity; public health and environmental services personnel store information concerning unusual outbreaks and patterns of illness; regulators of dangerous substances have records of atypical purchases of materials or equipment that might indicate a covert capability. By inter-linking these data resources, investigators can gain a more complete picture and can help address various problems more rapidly. This information can assist law enforcers in deploying resources more effectively and proactively. By forecasting future events based on this data, law enforcers potentially could anticipate strategic locations for deployment.\textsuperscript{31}
No matter how effective, complete reliance on exclusively domestic law enforcement to prevent bio-violence threats would leave unacceptable holes. Any illicit activities condoned by the host State would not be investigated by that State’s law enforcers. And there are serious doubts about most States’ capacity to investigate suspicious bio-activities even if those activities are wholly private. There is, however, an enormous problem taking expanded surveillance law enforcement techniques from the domestic sphere where data sources are jurisdictionally defined and where authority to use information is strictly defined. Thinking about expanded surveillance in the international sphere, notably in the absence of an authoritatively designated institution, complicates those techniques by orders of magnitude. Even if expanded surveillance could be effectively used to detect suspicious activities worldwide, who would (or even could) take appropriate action to forestall successful completion of those activities?

Moreover, a global system for preventing bio-violence must have authority to investigate suspicious activity in order to propound confidence in the system’s worldwide efficacy. A substantial problem has to do with what constitutes “suspicious activity.” Without explicit criteria, the risk of abuse or harassment is too substantial to tolerate. For investigations to be perceived as legitimate, there must be consistently applied reasons why they occur and, perhaps more important, why inspections do not occur. At minimum, failure to report violations of biosafety standards, denial measures, or related compliance obligations should be grounds for investigation. Failure to report any of the very few experiments that require international notification should also be grounds for investigation. ….

It is not likely that even effective expanded surveillance techniques will produce evidence that meets many States’ requirements of probable cause for a law enforcement investigation. Moreover, sovereignty constraints would inhibit any international effort to check out suspicious activity unless there is an already-negotiated right of investigation. Without authority to follow leads, law enforcement would be only as effective as the State that is the destination of those leads. Therefore, there needs to be sharply defined legal criteria for tracking down covert bio-violence preparations and, as discussed in Section IV, a legitimate authority to apply that criteria.

Critically, law enforcement investigations must be distinguished from arms control verification inspections. These terms have very distinct meanings with profound implications for preventing bio-violence. Most (not all) inspections are done to verify compliance with stipulated requirements or regulations – only rarely are inspections performed because there are suspicions
of non-compliance. Because verification inspections are designed to prove that breaches of stipulated requirements are not occurring, they must take place anywhere there are relevant capabilities to commit such breaches; verification of compliance therefore takes substantial resources. Law enforcement investigations are far more selective, and therefore resources can be more selectively targeted because they are premised on suspicions of non-compliance; a law enforcer must have something like probable cause. But law enforcement investigations inevitably raise something of a stigma whereas verification inspections typically do not.

During the 1990s in connection with the BWC, a Protocol was negotiated calling for inspections of facilities capable of processing lethal bio-agents on a random basis, i.e. declared facilities having such capabilities would form a pool, and particular facilities would be chosen at random for inspections. The BWC Protocol failed to come into effect in part because the plan for random inspections of declared bio-facilities would be very unlikely to uncover bio-violence preparations. Although policy arguments can be made in support of the proposed system of random inspections, it is clear that these inspections would do little to prevent bio-violence.

Thus, law enforcers worldwide must be authorized to investigate activities that raise suspicions of bio-violence preparations. The criteria for such investigations must be promulgated by an international body that is responsible for bio-violence prevention policies, as discussed in Section IV. Investigations should be rare. And as will be discussed just below, such investigations must respect the legitimate pursuit of bio-science and must be coordinated with policies for supervising bio-research that might have dangerous implications. Yet with appropriately stipulated criteria that are globally harmonized and judiciously applied, law enforcement investigations are the indispensable modality of all bio-violence prevention policies.

III. THE BIO-SCIENCE PARADOX

Does bio-science raise bio-violence risks? Unfortunately, bio-violence does not occupy a wholly separate realm from bio-science; they overlap in two important respects. First, there is the issue of potentially dangerous bio-research – might leading edge research, while offering enormous benefits to human health as well as potential vaccines or cures against bio-violence, also enable new forms of bio-violence by reducing hurdles that potential perpetrators must surmount? Second, there is the issue of bio-defense – do State programs for encouraging bio-
research pose a risk of disguising bio-weapons preparations, and when do military applications of that bio-research subvert global norms?

At the core of these questions is a paradox: to learn how life works is to learn how it is threatened and extinguished. Bio-science cannot produce cures for disease without, simultaneously, recognizing the disease’s capabilities, its vulnerabilities, and our own. The beneficent applications of bio-science are intertwined with their malevolent implications and cannot be disentangled at the level of fundamental science. To try to separate them is to try to separate sides of a coin.

In principle all biological knowledge can be used both for civil and military purposes. The knowledge needed to weaponise a germ is essentially the same as is needed to understand how that germ causes disease and how to create an effective vaccine against it.

This issue is not about tightening security against risks associated with sloppy bio-science, e.g., unprotected facilities that allow malevolent persons to gain wrongful access to dangerous pathogens and sophisticated equipment. This discussion is not intended to re-visit the need for measures to deny such access, to know where are dangerous pathogens and sophisticated equipment, to strengthen law enforcement, etc. But what if bio-scientists do everything right; does the essence of their work -- opening ever more fascinating windows into the structure of life itself -- necessarily open ever more dire potential for bio-violence?

Telling bio-scientists to pursue science in compliance with reasonable security measures is one thing; telling them that their science might produce dangerous knowledge is another message altogether. Indeed, denial and law enforcement policies are explicitly designed to distinguish illicit bio-violence preparations from legitimate science and to avoid interference or even unnecessary supervision of scientific pursuits. How can policies to control the direction and application of bio-science be promoted without constricting bio-science progress, or should such policies even be considered?

This paradox of advancing bio-science has deeply rooted metaphors: to eat the apple from the tree of knowledge is to be banished from primal innocence. Bio-science progress in the last few decades, marked notably by the cracking of the human genome and accelerating with no conceivable end in view, is teaching us about the architecture of life itself. That appropriation of knowledge poses humanity’s most significant confrontation with our ability to advance our intelligence without inevitably shedding our morality.
So, should research proceed into the genetic properties of, for instance, Ebola in order to identify what makes it lethal and incurable in primates? Should such research include inquiry into how the virus could be fused with more contagious viruses that might result in a superbug with Ebola’s lethality but far more readily spread? Does the legitimacy of this research depend on whether it is undertaken by a State’s military establishment under a bio-defense program, a State’s health establishment, or by private scientists? Maybe the answer is that some research is too dangerous and has too little upside potential to be allowed. If certain lines of experimentation are prohibited, then it might be easier to distinguish permissible from offensive weapons preparations.

Even if research should proceed, should it be published? For example, Australian scientists working with mousepox (a relative of smallpox non-lethal to humans) injected a gene – Interleukin-4 – and produced a “supercharged disease” for which vaccines were wholly ineffective and that, as a result, had a 100% fatality rate among exposed mice. Notably, the scientists published their research results in the popular science press without advance consultation.\(^{37}\) Very recently, scientists extracted the 1918 Spanish Flu virus from victims’ corpses, decoded its genetic sequence, and posted the virus’ fully decoded map on the internet. Although samples of the virus are strictly controlled, its component DNA strands are widely available, and few bugs are as easily subject to regeneration as influenza.\(^ {38}\)

Notice: these situations could provoke contradictory responses. If bio-defense research is wholly secretive, it might be more suspicious than if in the public domain. Concealing sophisticated bio-research amplifies anxiety that it is designed to advance an offensive bio-weapons program. By contrast, the mousepox or Spanish Flu research might have been less troubling if done more confidentially. Thus, open exchange of ideas encourages scientific progress and builds confidence that purported peaceful intentions are not a ruse, even as it raises risks that perpetrators of violence could gain insights that enable a catastrophic bio-attack. There are reasons to object both to full secrecy and to full revelation – but a policy resolution that accommodates both sets of objections is difficult to decipher. That difficulty is multiplied by the fact that bio-research often puts at stake both vast proprietary interests as well free speech rights.

And the most paradoxical part of the paradox, especially amid a discussion advocating the need for legal action, is that scientific progress inevitably outpaces the incremental growth of law. Moreover, bio-science’s risks are inherently trans-national; any legal policy that respects
the accelerating globalization of both bio-science and communication must be implemented worldwide.\textsuperscript{39} But as development and application of law must tread gingerly through the thickets of an anarchic international system, there is a real danger that law just can’t keep up. This disparity means that to propound commitment to older legal frameworks might seem retrogressive, but to propound adaptation to scientific change might jeopardize the durability of hard-fought legal norms. Indeed, recent debates regarding the Biological Weapons Convention demonstrate these conflicting propensities.\textsuperscript{40}

This much is certain: scientific progress wins. Few of us would so much as consider legislating constraints on bio-science, but even if we wanted to pass a law to contain bio-science, the law would soon be washed away by an inexorable surge of knowledge.

**Bio-Defense / Bio-Offense**

In the bio-violence policy arena, no term is used more often with less meaning than \textit{bio-defense}. Its proponents use the term to apply to research on new vaccines and other protective measures that will limit harm from bio-violence attacks. Its critics use the term to describe government-funded research into potentially new military applications of bio-science. Both would agree that developing vaccines to inoculate troops from anthrax is \textit{bio-defense}; but what of research to better understand anthrax’s mechanism of lethality; what if that research entails development of a “mock” anthrax bomblet to test that mechanism and the efficacy of vaccines?

The \textit{bio-defense} question is not easily resolved: may a government engage in bio-science research in order to identify potential bio-threats and to devise protective measures against those threats if that research has direct and obvious potential for a bio-weapons development program? No government should be castigated for trying to protect its people from bio-threats. The political implications of foregoing available research opportunities and then suffering the unprotected consequences of an attack are beyond calculation. Thus, any multilateral system that would command a State to refrain from such measures is destined to force non-compliance.

Many bio-defense projects could generate an offensive capability.\textsuperscript{41} To test bio-agent detection systems, infectious microbes are often produced and dispersed. A vaccine against anthrax or plague is not only a defensive tool, it can also support development of an offensive bio-weapons capability as an aggressor would need a vaccine to protect its own troops. The dual-use problem makes it very difficult to draw a clear line between legitimate and illicit
research; it is often only a matter of intent whether an experiment is offensive or defensive. The concerns here are both actual (should States undertake advanced research that can discover truly awesome weapons capabilities?) and perceptual (even if a State is engaged in wholly defensive research, does that engagement undermine confidence in multilateral compliance with the BWC such that other nations believe that development of offensive capabilities is justified?).

The issue turns in great part on the meaning and significance of the BWC Article I which prohibits development of microbial or other biological agents or toxins that have no justification “for prophylactic, protective, or other peaceful purposes.” It admits of no exception, but it provides no amplifying guidance as to what activities comprise these prophylactic, protective and peaceful purposes and what activities are not so covered and therefore prohibited. Not surprisingly, it is United States policy that provides the grist of controversy. Critics of some U.S. bio-defense activity suggest that U.S. military initiatives might, if pursued to their logical end, undermine the scope of and commitment to Article 1. In response, proponents suggest that the BWC is sufficiently flexible to tolerate some military applications of bio-science; if it’s not, the BWC should be adjusted, not bio-defense efforts.

Questionable initiatives include building and testing a cluster munition for spreading bio-agents;42 constructing a facility to produce microbial anthrax simulants; developing plans for genetic engineering of a vaccine-resistant strain of anthrax;43 pursuing a long-term effort to produce weaponized anthrax spores for defensive testing;44 secretly operating leading edge bio-research programs at former nuclear weapons facilities;45 pursuing a program to sequence over twenty classical bio-weapons microbes; and developing taggant bio-weapons – use of a microorganisms modified to exhibit an unusual behavior (e.g., "glowing" genes) to secretly track or even target a building, vehicle, or other object.46

Other activities that focus on less lethal bio-agents have clearly been pursued for military purposes, including exploring the potential of genetically engineered anti-material agents (GAMAs). Industry has long used microbes for bio-remediation (to clean up oil spills); genetic engineering could open possibilities to degrade the petroleum in an enemy’s repositories, to corrode rubber tires and gaskets on enemy vehicles, to abrade moving parts, or to impair highways. The US federal research system capable of pursuing GAMA offensive research and weapons production includes a significant testing and bio-reactor (fermenter) capacity, as well as bio-defense experiments to prepare genetically engineered microbes for field release.47

Notably,
the Joint Non-Lethal Weapons Program (JNLWP) request for the Navy Judge Advocate General’s approval of research on offensive uses of anti-material bio-weapons was denied because it would violate the BWC.

Concerns go beyond classified military research. Large funding has been allocated to defenses against weaponizeable agents and is radically escalating: from 2002 to 2004, research funding on predatory bacteria and extremely lethal viruses, through both military and civilian programs, increased by over 2,000 percent.\(^{48}\) Altogether, 300 institutes and 13,000 individual scientists have direct access to bio-weapons pathogens including anthrax, brucellosis, glanders, plague, melioidosis, and tularemia. On bioterrorism-related research alone, the U.S. has increased spending more than thirty-fold from $53 million in 2001 to $1.6 billion in 2004. The current program includes research to develop medical biological agent countermeasures.\(^{49}\)

Some of these funds are going to construction of new bio-containment laboratories equipped with filters, barriers, and air-handling systems so that researchers can handle deadly and incurable pathogens while minimizing the risk of accidental infections of lab workers or releases from the facilities that could endanger public health or the environment.\(^ {50}\) According to ???, these “research and development efforts constitute an indispensable investment toward proper domestic preparedness against potential uses of biological or chemical weapons.”\(^ {51}\) Yet, recent initiatives raise novel concerns: for example, the National Biodefense Analysis and Countermeasure Center (NBACC) at Fort Detrick in Maryland has the mission to anticipate, prevent, respond to, and recover from current and next-generation biological threats by advancing the scientific community's knowledge of potential bioterrorism.\(^ {52}\)

The U.S. government has without exception avowed its support for the BWC. Critics allege, however, that to allow classified research exploring applications of bio-technology to the development of bio-weapons would poke a hole through its normative prohibition – a hole so enormous that it would effectively subsume the prohibition entirely. Accordingly, preservation and strengthening of norms against certain types of weapons is the only way to stop militarists from self-justifying whatever weaponry they find potentially useful; that technology is opening new possibilities only reinforces the need to stringently distinguish permissible from impermissible weaponry. As the Russian bio-weapons expert Ken Alibek has pointed out, when you “start modelling or mimicking actual weapons, you come into very sensitive areas” that can imply offensive preparations, especially if the details are kept secret.\(^ {53}\)
The Need for Translucency

Policies to address emerging bio-science risks – policies that complement denial and law enforcement policies – must recognize that scientific progress will proceed regardless of legal norms or constraints, and no nation that has capabilities and political will to develop vaccines and other protective measures against bio-attack will tolerate internationally-imposed constraints on those defensive pursuits. Moreover, the extreme expense of monitoring bio-science research in order to distinguish peaceful purposes from hostile purposes must be weighed against the low likelihood of complete and accurate determinations. For these reasons, implementation of arms control transparency policies is inappropriate.

The term transparency refers to policies that enable adversaries to verify each other’s compliance with negotiated obligations. If stipulated activities are transparent, then each party can know what others are doing and can enforce its rights in any controversy without delay. The mechanism of transparency, developed in connection with superpower nuclear weapons control, typically involves inspections: representatives of interested parties (or international inspectors) are entitled to scrutinize facilities having capacity to make a controlled weapon.

To achieve transparency with regard to bio-science capabilities would require gathering and verifying copious information about facilities capable of producing bio-violence devices. But, in contrast to nuclear weapons verification, the number of such facilities is essentially limitless, and it is easy to hide wrongful preparations even at facilities that are being monitored. Perhaps with literally thousands of well-trained inspectors, it might be possible to monitor activities at key bio-science installations, although it should be noticed that the best trained and most broadly authorized United Nations inspectors failed to discover Iraq’s bio-weapons program in the early 1990s until receiving a tip from an Iraqi weapons official. It borders on the absurd to devote comparable resources to inspection of every State having sophisticated bio-science capabilities.

Moreover, the kinds of places and activities that would likely be subject to inspection are simply not where or how anyone expects bio-violence preparations to occur. To focus on them would far more likely interfere with wholly legitimate bio-science pursuits than on potential criminality. In other words, even if massive resources were dedicated to monitoring declared bio-science activities, those resources would at best prove that legitimate bio-science is, in fact,
not engaged in bio-violence preparations; it would not tell us much about where such preparations are in fact taking place nor give us much advantage in our efforts to stop it.

Translucency, by contrast, refers to a set of policies that do not seek to verify non-production of weapons (except in unique contexts) but which are designed to overcome risks associated with opacity. The heart of these policies is to generate an information flow that might enable detection of wrongful activity as well as to deter easy pursuit of bio-violence. Notably, these policies are hardly novel for bio-scientists operating in States with highly-developed science and pharmaceutical sectors -- indeed, the concept here is to globalize these basic mechanisms for enabling non-intrusive oversight.

Translucency policies are built on the following presumptions:

1. Bio-research involving listed bio-weapons agents, posing a unique threat of weapons application or designed for military applications, must not be performed in absolute secrecy.

2. Dispersal of bio-agents, or preparations to do so, for the purpose of harming living things is prohibited unless internationally sanctioned.

Importantly: application of all policies based on these presumptions depends entirely on the existence of a legitimate judge authorized and capable of making nuanced decisions – a hugely critical point to be returned to below.

No Absolute Secrecy

The central reason for prohibiting secrecy is to enable accountability: someone would always be able to trace research activity back to its source. Secrecy in biodefense programs raises suspicions and could promote a race for offensive capabilities under cover of defense. Prohibiting secrecy raises confidence that bio-research activities are not undertaken to advance bio-violence. And prohibiting secrecy has deterrent value especially for national bio-defense programs as the challenge of keeping wrongful intentions secret would escalate as would the implications of trying to do so. Accordingly, no bio-research should be \textit{black-box}; at minimum, it should be subject to national processes for official oversight. Even where national authorities deem it appropriate to classify (hold confidential) bio-research, classification should be limited to the details of that research; keeping secret the fact of classification should be prohibited.
But prohibiting secrecy also has implications for important proprietary and privacy interests. Accordingly, it is essential to differentiate: (1) research with significant implications for bio-violence from the vastly larger amount of research that does not have such implications; and (2) the existence of that research from its specific contents or results. In truth, very little research need be disclosed, and it is the fact of research not its content – its location and basic purpose not its methodology or results -- that should be disclosed. Disclosure would be to national authorities except in rare cases involving extremely dangerous research or research deliberately focusing on military applications that should involve international disclosure.

Experts have differing opinions on the definition of “potentially dangerous bio-research.” The problem is not so much the difference of opinions but the absence of any authoritative process to resolve them. Of course, even if precise criteria could be identified, their application to specific experiments would demand constant renewal. Crucially, scientists (as well as officials having supervisory responsibilities) must precisely know whether that criteria apply to specific activities. The principle of legality requires that for a prohibition to be enforced, its application must be judiciously limited and sufficiently precise so that purported violators should have known their conduct crossed permissible lines. Legal obligations cannot be imposed unless they are precisely and legitimately defined. Also, the criteria of dangerous research must be globally uniform – if States have different criteria of potentially dangerous bio-research, there will be confusion as well as a “race to the bottom” as States compete to be the least restrictive and therefore most attractive for emerging bio-science.

There is vast misunderstanding about what information should be disclosed and the process of handling and storing that information. Most research has value: proprietary value perhaps for development of pharmaceuticals, career value to the researchers, etc. Moreover, the process of disclosing information could intrude into professional and personal privacy. Nuclear physics research has long coped with such intrusion, but there is little justification for replicating that experience in connection with bio-research. Confidentiality is essential; distinguishing secrecy from confidentiality is mandatory. Perhaps the best example of a system involving strict disclosure requirements with effective protections of confidentiality is the Chemical Weapons Convention’s extensive reporting requirements to the international Organization for the Prohibition of Chemical Weapons – a carefully honed balance of the need to
verify non-production of chemical weapons with the need to sustain chemical industry participants’ proprietary rights.\textsuperscript{61}

\textbf{No Unsanctioned Dispersal of Bio-Agents or Preparation for Dispersal}

The BWC prohibition against weaponization of bio-agents is the preeminent example of a hugely important norm being chipped at by technological progress. Organic farmers disperse microbes on crops in lieu of chemical pesticides; as previously mentioned, microbes are widely used to remediate petroleum and other hazardous waste releases; self-replicating processes (whether biological or mechanical is increasingly a semantic distinction) are on the horizon for information and other technology purposes. If, for example, a military can readily use microbes to clean up oil spills, how reasonable is it to prohibit their use against an adversary’s oil supplies? If highly destructive chemicals can be dropped on coca fields, is it reasonable to prohibit dropping microbes that have far less toxic implications?

These problems about how bio-agents can be used become even more paradoxical in connection with merely doing studies or assessments of efficacy. Retention and reinforcement of norms that prohibit the hostile applications of bio-science is mandatory. But how can those norms operate when hostile applications can be distinguished from legitimate bio-science only retrospectively? It may be reasonable to define a spectrum of activities involving lethal bio-agents from mere handling of a disease strain, to studying it and preparing vaccines, to manipulating its genetic properties, to developing a weapons capability, to weaponization. Manifestly, activities at the mere handling stage are legal; activities at the weaponization stage are illegal; where to draw the line in the middle is more problematic.

The “slippery slope” implications here are enormous. Most people might be supportive of development of mood-altering pharmaceuticals for selective use by trained medical professionals; widespread use for military purposes is another matter altogether. Again, agricultural use of microbes by organic farmers is one thing – their use as agro-weapons is very different. If military use of any bio-agents is permitted for any purpose even for non-hostile purposes, how can the prohibition against weaponization be sustained as the primary bulwark against bio-weapons?

Some criteria are easy: assembly or loading of a warhead or other mass dissemination device with lethal bio-agents should be prohibited; any delivery mechanism using bio-agents for
hostile purposes or in armed conflict is prohibited; open-air dissemination without the local population’s consent should be prohibited just as non-consensual testing on human subjects should be prohibited. But the gray areas are rapidly expanding, and these easy criteria will decreasingly resolve myriad applications of bio-agents in commercial, law enforcement, or military contexts. Resolving all these questions is probably impossible; it’s certainly beyond the scope of this discussion.

Far more certain is that few legal rules or norms can fulfill their purpose effectively without some body that is authorized and capable to make decisions about how to apply such rules or norms. The central requirement with regard to dispersal or bio-agents or preparations for doing so is to shift the locus of decision-making from national to international authorities. That is, if using bio-agents to eradicate coca fields is permissible for one State’s military, it should be permissible for any State’s military; if doing experiments to identify how anthrax might be effectively disseminated is prohibited for one State, it should be prohibited for any State. That is, for activities that directly engage the BWC prohibition against weaponization, the standards should be global and the decider of where to draw the line should be international. Accordingly, weapons-simulations programs/experiments must be reported internationally; conduct of weapons-simulation programs without disclosure is prohibited.

IV. ON GOVERNANCE AND JUSTICE: A GLOBAL COVENANT FOR PREVENTING BIO-VIOLENCE

Preventing bio-violence is more than a set of policies, more even than a strategy – it is where the right to health and the separate right to security intersect. It is an avowal of a collective (humanity) right as the foundation for a global administration that integrates promotion of bio-science and public health with security-based responsibilities. This right demarcates, perhaps more explicitly than ever, a unity of human purpose transcending boundaries of geography and ethnicity even as it compels finely-tuned governance modalities for our most profound scientific pursuits. 62

The right associated with bio-violence prevention is this: humanity is entitled to every State’s commitment and best effort to implement prevention policies. As perpetrators will explore and likely discover the weakest link in global defenses, and as a contagious disease will not be limited to any location, all humans share a right which insists on collective action to
satisfy humanity’s shared needs for health security. As the necessary actions are inherently trans-national (e.g. international law enforcement cooperation; implementation of bio-science translucency policies), their efficacy depends on universal effort. And most important, in connection with bio-science the future is the present. Failure or non-compliance by any authority in meeting its obligations will, sooner or later, jeopardize us all.

The pursuit of bio-violence prevention is a shared human endeavor, demanding a shared human response through shared institutions. It is hereby proposed that bio-violence prevention be advanced via a global covenant that propounds: (1) common but differentiated responsibilities for combating pandemic disease whether natural or violent; and (2) governance modalities that reflect and promote evolving species-wide strategies in ever richer dimensions of complexity. This global covenant for bio-violence prevention portends a new chapter in the human species’ most basic and most long-lasting struggle against lethal microbes and offers a new vision of how to globally organize strategic security.

**Common But Differentiated Responsibilities**

Simply stated, it is illegitimate to compel global pursuit of policies for preventing bio-violence in isolation from the far larger pursuit of policies to combat pandemic disease. HIV/AIDS, TB, malaria, emerging infectious diseases, poor health infrastructure, and food security ravage our species -- bio-scientists warn of an imminent pandemic. A sweepingly contagious virus (e.g. avian flu or SARS) or even a slower-acting but incurable disease (drug-resistant tuberculosis) would devastate populations already suffering from widespread health impairment; developed nations in North America and Europe would fare only slightly better. Of course the human species has always faced disease crises, but for the first time we can refuse to accept rampant health catastrophe as an inevitable condition.

The global covenant for preventing bio-violence is forged from the recognition that the human species faces manifold and highly divergent disease threats and the assertion that policies for preventing bio-violence must be included within and complimentary to a global health commitment. Although the myriad debates about how to combat disease and what tactics might be comparatively advantageous are far beyond the scope of this discussion, it suffices to say that preventing bio-violence is important but it is a facet of a larger policy agenda that elevates health as a security priority and compels efforts to address global health disparities. Accordingly, each
State is obligated, according to its capabilities, to cooperate in the detection, mitigation, and containment of disease; from all States collectively is the obligation to develop legal mechanisms to facilitate international flows of research, assistance and cooperation.  

The prime reason for inclusion of bio-violence prevention policies within a larger global health commitment is the obvious disparity of resources worldwide. Scarce public health resources must be allocated for all diseases, proportional to the level of risk and sensitive to gaping differences of capacity. Risks of bio-violence must be assessed along with risks of natural disease but with one important caveat: the assessment of potential harms of bio-violence must include the likely consequence of incomparable levels of panic and political instability. Thus, resource disparities must not excuse disdain for or inattention to reasonable measures to prevent diversion or wrongful use of pathogens. If bio-violence prevention is seen in this larger context, and if the inherent and unavoidable international security character of public health challenges is appreciated, decisions about how to allocate responsibilities and opportunities can be rationally formulated.

Promotion of bio-science is fundamental to the advance of human well-being, development and security. The Millennium Development Goals call for the application of science and technology for development and emphasize the importance of collective efforts in this regard. Yet, bio-science can extend life or destroy it. This era is witnessing the genesis of bio-science revolutions that will likely transform human life but which could inflict global calamity if malevolently deployed. These revolutions are both horizontal and vertical. Horizontally, bio-research and pharmaceutical production are proliferating rapidly across the planet with a concomitant multiplying of the diversity of persons engaged in these sectors. Vertically, escalating bio-research offers the potential to discover elemental principles of pathogenicity that could enable cultivation of a disease of such devastation that civilization could be fundamentally maimed with attendant risks of economic collapse and political upheaval.

The global spread of legitimate bio-science is a social good, and policies to encourage that spread should be implemented. There must be a strong presumption against restrictions on the distribution of scientific knowledge, against trade restraints on the distribution of pharmaceuticals and other biological products, and against constraints on the movement of bio-scientists. Yet, because of the risks associated with bio-violence, bio-science must be advanced along with a commitment to protect against its hostile applications. Burgeoning opportunities for
improvements in bio-science and public health should be linked to fulfillment of bio-security obligations: development funding in bio-science activities should be contingent on implementation of security controls; correspondingly, pro-active implementation of specific controls and cooperation with relevant international organizations should encourage developmental support. With opportunities and encouragement necessarily comes responsibility -- no matter how great the need, no one should be able to obtain benefits by ignoring risks. This progressive linkage is the tangible core of the global covenant.

Relevant prevention measures have been elaborately discussed. Important here is to assert that targeted assistance and resources are essential. Among such assistance and resources, attention should be given to international efforts for

- Promoting bio-science education and centers of excellence in bio-science
- Strengthening universities, research institutions, academies of science and other scientific networks
- Establishment of joint research and development program for vaccines and other capabilities to protect against disease with special focus on HIV/AIDS, TB, and malaria;
- Building of public health infrastructure and capacity, and development of preparedness and disease outbreak response assessment capabilities;
- Creating and sustaining disease monitoring, notification, and surveillance systems;
- Development of public health communication systems that are connected with global communication systems; and
- Raising awareness and understanding of disease, whether deliberate or natural, through *inter alia* strengthening the capacity of civil society.\(^\text{65}\)

The essence of this global covenant, therefore, is that measures to protect against the misuse of bio-science and assistance to promote human security must be inter-linked. There is a need for balance: Addressing bio-violence concerns inappropriately could undermine development of bio-science and technology with catastrophic effects. Developing bio-science but failing to address bio-violence concerns could lead to catastrophe and undermine confidence in science. Addressing all these concerns in harmony is mandatory for humanity’s security.\(^\text{66}\)

**Global Modalities for Administering Bio-Violence Prevention**

The consistent thesis throughout this discussion is the absence of and need for a global authoritative structure to define criteria, facilitate implementation and execution of policies, promote trans-national and trans-institutional communication and coordination, monitor
compliance, and make key judgments of what behavior threatens international peace and security. No such authoritative structure exists; to believe that much progress can be made without that structure is fanciful.

**Various Concepts for Global Administration**

The most notable idea asserted to fill this void is for an organization that would perform arms control functions analogous to the functions performed by the International Atomic Energy Agency (nuclear weapons control) and the Organization for the Prohibition of Chemical Weapons (chemical weapons control). These organizations undertake complex responsibilities to verify non-production of a type of weapon of mass destruction -- as bio-weapons are the third category of the WMD cluster, there is a simple logic to advocating an “Organization for the Prohibition of Biological Weapons” or OPBW. However, verification of non-production of biological weapons is not a core component of preventing bio-violence. To so verify would, as earlier discussed, entail exorbitant resources because bio-weapons can be made and disguised virtually anywhere. More centrally, knowing that bio-weapons are not produced at a facility would be of scant benefit in detecting if and where such weapons are actually being made. Simply stated, an OPBW would require a vast bureaucracy subject to intricate and confining rules, expensive and intrusive with little upside security benefit. Its only commendation is consistency with other arms control regimes, but that rationale does not justify the expense and effort.

Instead of creating a new organization, a quite different idea is to centralize responsibilities in global health organizations, primarily the World Health Organization along with the Animal Health Organization and the Food and Agriculture Organization. There is considerable logic in vesting these U.N. bodies with responsibilities that are so patently related to public health; these organizations should be responsible for promulgating standards for pathogen and laboratory security and for assisting States in their implementation. These bodies are unsuited, however, to undertake responsibilities associated with detecting and interdicting wrongful conduct. These organizations are most definitely incapable of finding perpetrators of violence, working with law enforcers, overseeing bio-science, or investigating suspicious activities. Indeed, while these organizations have critical roles in preventing bio-violence, endowing them with over-arching authority would either put them in uncomfortable positions of having to be law enforcers while trying to provide health services to all persons in need or would
limit preventing bio-violence to exclusively public health functions. Neither outcome is appropriate.

Because law enforcement is central to preventing bio-violence, it has been proposed that Interpol take authoritative responsibility for preventing bio-violence. There obvious logic in having Interpol coordinate standards and training for law enforcers. Moreover, Interpol is actively pursuing its Program on Preventing Bio-Terrorism – by far the most sophisticated global effort related to threats associated with the misuse of bio-science. Yet, centralizing comprehensive responsibility in Interpol would pose the converse problem just discussed with regard to public health organizations. Certainly, preventing bio-violence entails substantial and critical contributions from law enforcement, but other communities that must make contributions are likely to be nervous about centralizing authority in the police.

A related yet more sophisticated proposal would be to advocate inter-organizational coordination among WHO and Interpol with important contributions from other public health organizations as well many other organizations with specialized expertise and missions. At this time, nearly thirty international organizations have some responsibility that is relevant to bio-violence prevention. These international organizations would have to be coordinated, and the standards they promulgate would have to be harmonized. The objective would be an integrated network of organizations working cooperatively but with specialized expertise to carry out distinct aspects of bio-security, with mutual representation and assistance. As each organization has its own substantive mandate and professional constituency, each can represent one or more component parts of the global bargain. This, in turn, suggests an on-going process of deliberation, negotiation, and joint implementation on a plane that respects States’ interests but is not directly subject to the political vicissitudes that plague inter-State diplomacy.

In theory, inter-organizational coordination makes substantial sense. In reality, however, each of these organizations has a limited mandate and is responsible to its own governing bodies for fulfilling that mandate. Inter-phasing these disparate functions as pursued by disparate groups of experts -- and holding these myriad organizations in a common structure over time – is not currently realistic. Moreover, even if inter-organizational coordination is feasible, there is the larger question of who would undertake enforcement responsibilities in connection with actual suspicions of bio-violence preparations or, worse, in connection with a bio-violence
attack. In the array of organizations that might comprise this bureaucratic net, none would be expressly authorized to address the hardest and most critical cases.

The United Nations

Bio-violence is, ultimately, a threat to international peace and security; policies for preventing bio-violence should be administered, therefore, by the only body with global responsibility that is sufficiently broad and powerful: the United Nations. Indeed, the competing and cross-cutting considerations that are affected by bio-violence prevention -- the ubiquity and undetectability of pathogens, the shared vulnerability of humanity to disease, and the global inter-activity of bio-science -- all portend a new chapter in the human species’ most basic and most long-lasting struggle against lethal microbes and offer a new vision of how to globally organize strategic security. These remarkably far-reaching tasks that are simultaneously promotional and regulatory of science and commerce, that entail potential intrusions on sovereignty and perhaps assertive enforcement action, and that must be integrated into humanity’s broad policy agendas for combating pandemic disease – all these must be undertaken by the only body properly authorized and capable of such a profound endeavor.

Within the United Nations, a logical approach would be to divide responsibility among three subsidiary bodies.

- The United Nations Committee on Bio-Science (UNCBS) would be responsible for assisting developing countries in using bio-science and bio-technology for development. It would also follow legal, scientific and technical developments relating to bio-science, technology and applications in order to provide technical information and advice to Member States, international organizations and other United Nations offices. The UNCBS would be responsible to ECOSOC and the General Assembly. Within it is the:
  - Research and Right to Development Section -- responsible for promoting and protecting the right to bio-science development. It does so by conducting research and identifying strategies to promote such development especially in States with emerging bio-science sectors. This section also prepares and distributes reports and publications on international bio-science activities and on international law pertaining to bio-science.
  - Capacity Building and Resource Mobilization Section -- develops, implements, monitors and evaluates advisory services and other technical-assistance projects at the request of governments, to strengthen the capacity of national institutions, supports implementation of bio-science development initiatives, and prepare reports on bio-science capacity building. This section also works to obtain stable, predictable and flexible funding from donors, and strengthens relations with
donors by regularly exchanging information, organizing annual consultations and visiting donors capitals; and follows up on pledges and contributions.

- Global Resource Center for Bio-Violence Prevention

  The United Nations Office of Bio-Violence Prevention (UNOBVP) focuses on assisting Member States to implement measures against bio-violence and to facilitate concerted action among States and United Nations bodies against bio-violence. The UNOBVP assists the Security Council, the Department of disarmament Affairs and the 1540 committee and the counter-terrorism committee The four pillars of the UNOBVP work programme are:

  - Research and analytical work to increase knowledge and understanding of bio-violence issues and expand the evidence-base for policy and operational decisions;
  - Normative work to assist States in the ratification and implementation of the international treaties and guidelines of international organizations, the development of domestic legislation on bio-violence, and the provision of secretariat and substantive services to the treaty-based and governing bodies;
  - Field-based technical cooperation projects to enhance the capacity of Member States to counteract bio-violence;
  - Provision of support to the fact-finding and investigatory mechanisms of the Commission on Bio-Violence. Such support includes special rapporteurs, special representatives and experts, and working groups mandated by the Commission and/or the United Nations Security Council, with the aim of documenting violations of international obligations that might be relevant to bio-violence prevention so as to draw the attention of Member States, the United Nations and other international organizations, and the public to such violations.

- The United Nations Commission on Bio-Violence (UNCBV) is made up of Member States on a basis that reflects the security, science, and development issues raised by bio-violence as well as reflects the inherent global interest in its prevention. The Commission will fill the gap within the UN system as to helping States with regard to bio-violence prevention by facilitating an institutional and systematic inter-connection among the network of assistance and expert bodies that might be relevant. The U NCBV’s purpose is to bring together all the major actors in a given situation to discuss and decide on a long-term bio-violence prevention strategy. Although the U NCBV is an advisory body, its recommendations will carry weight because of the diversity and relevance of all those participating – including members of the Security Council, the leading bio-science sectors, top financial donors and key institutional players. The Commissions three primary responsibilities are:

  - To pursue suspicious activity possibly indicative of bio-violence by working closely closely with national and transnational authorities involved, recognizing the importance of national ownership of the bio-violence prevention process;
  - To respond to requests from the Security Council concerning threats of bio-violence and where appropriate to recommend that the Security Council take appropriate action in the face of demonstrable bio-threats to international peace and security;
In the event of a bio-violence attack, to facilitate and provide assistance to Member States, bodies of the United Nations, other international organizations, and major interested parties including such measures as might be appropriate to mitigate harm, limit the spread of disease, and apprehend perpetrators.

V. PRINCIPLES, OBLIGATIONS AND RECOMMENDATIONS

A. 1. Bio-violence is the infliction of harm by the intentional manipulation of living microorganisms or their natural products for hostile purposes. Disease and strife are the Achilles Heels of our age; bio-violence is where they intersect -- a crime against humanity without regard to whether the perpetrator is a State or a person and without regard to the jurisdiction where such bio-violence occurs.

2. Bio-terrorism is a many-faceted thing that can involve any of numerous bio-agents, technologies, and dissemination systems. Accordingly, strategies to prevent bio-violence should be similarly many-faceted, capable of selective preventive measures and responses to specific types of attacks.

3. Throughout the 20th Century, various States developed capabilities for -- and in some cases used -- bio-violence devices deliberately contravening normative prohibitions of such conduct. Accordingly, strengthening that normative prohibition is both necessary and insufficient to prevent bio-violence.

4. The Biological Weapons Convention of 1972 is the most vital international instrument relevant to bio-violence but key provisions have uncertain scope and are incomplete with regard to threats of non-State bio-violence, and efforts to strengthen the BWC are diplomatically stymied with regard to non-productive issues of verification. Accordingly, new modalities to prevent bio-violence should be put into force separately yet consistently with the Biological Weapons Convention.

5. Policies to prevent bio-violence are essential along with vulnerability reduction measures, but prevention policies might have potential to obstruct accelerating bio-science opportunities that create benefits for human health. Accordingly, policies to prevent bio-violence must only minimally burden the advance and spread of legitimate bio-science.

6. Bio-violence is a global threat that compels global policies, and these global policies compel nations to cooperate with less regard to their specific national prerogatives. The factors that have contributed to policy failures with regard to bio-violence prevention have created a most convoluted knot that won't conveniently unravel. The issues here are intricate and embedded in uncertainty, requiring elaborate twists and turns through policies that implicate science, diplomacy, and law enforcement.

B. 7. It should be difficult to gain wrongful access to refined pathogens, sophisticated bio-equipment, and advanced bio-laboratories. These denial policies must be directed at misuses of biology and place only minimal burdens on legitimate science. Their costs must be weighed against their limited benefits.

8. Access to laboratory specimens of readily weaponizeable pathogens should be controlled. Lists of such pathogens should be authoritatively prepared and updated by the World Health and Animal Health Organizations. These lists should be linked to standards that
govern how pathogens are to be handled, marked and stored. Every State should incorporate these lists into their national laws and regulations as relevant to carry out bio-violence prevention measures.

9. Proper record-keeping is absolutely essential to identify and track the location of dangerous pathogens. All States should be obligated to identify locations where refined specimens of violence-usable pathogens exist and to provide this data to an international body. Pathogens markers should also be reported and recorded. If pathogens are transferred, international databases should track and oversee this movement.

10. Bio-laboratories should be safeguarded to foil criminal activity, including measures to augment physical security and containment. Bio-medical and bio-science facilities where select pathogens or critical equipment are regularly used or stored must be identified. Only facilities that are properly registered may possess such items. Registration must be contingent upon implementation of sufficient mechanisms for safe operation including barriers to diversion. WHO and OIE guidelines for laboratory biosafety and biosecurity, including personnel access restrictions and record keeping and reporting requirements, should be legally binding for all registered bio-laboratories.

11. Advanced bio-laboratory equipment that is critical to effective weaponization should be tagged with positioning devices that reveal its location so as to enable law enforcers to track equipment that is operated outside of authorized facilities and to control the transfer of requisite materials and technologies. Databases that record the location of such equipment would be a deterrent to perpetrators who could not be sure if their use of that equipment might reveal the location of their covert preparations.

12. Persons that have knowledge that is uniquely vital to dangerous uses of bio-science should be trained and credentialed; access should be restricted to anyone else.

13. Transfers and movement of select pathogens or critical equipment should be supervised and tracked in order to prevent their smuggling or diversion; international standards for packaging and screening and for preparing appropriate records and reports should be authoritatively implemented. Carriage of pathogens should be regulated; carriers should be monitored for compliance with handling and storage guidelines. Uniform labeling of pathogens and equipment in transport is essential.

14. National implementation of denial policies entails establishing a system to register bio-science entities within the scope of national jurisdiction and providing strict penalties for its evasion. Official supervisory bodies comprised of bio-science experts should be linked to complementary oversight bodies responsible for advancing public health and scientific progress. National legislation should incorporate binding international requirements into the national system.

15. Bio-weapons stockpiles in the former Soviet Union (and perhaps elsewhere) must be safely and securely disposed.

C. Pursuant to both United Nations Security Council Resolution 1540 and to the Biological Weapons Convention Article IV, every State must criminalize bio-violence preparations and activities with procedures for appropriately including subsidiary crimes, prohibiting political defenses, extending jurisdiction, and enabling legal cooperation
17. Law enforcers must be properly authorized to detect and interdict wrongful activities that might contribute to commission of bio-violence. Criminal prohibitions should apply if behavior is done for hostile purposes, not to activity that is truly inadvertent. The scope of legal jurisdiction over such crimes should broadly reach the behavior of legal entities (e.g. corporations) and enable prosecution of participants in trans-national conspiracies. Moreover, internationally available capacity-building programs to equip and train law enforcers are required.

18. Ascribing the status of criminality to advance preparations for actual use of deadly agents raises the risk of snaring legitimate, even compelling, activities within the prohibition; overbroad attributions of criminality could stifle life-saving and economically valuable progress. It is imperative to distinguish wrongful preparations from legitimate science, pharmaceutical production, or even mere flights of imagination. National penal legislation should target pre-attack preparations for bio-violence by providing that receiving, supplying, or smuggling weapons precursors, critical materials, or critical equipment is presumptively criminal, unless that activity is declared.

19. It is imperative to detect illegal preparations early. The challenge here is how to know the unknown -- how to detect covert behavior. Expanded surveillance aims to identify anomalies that suggest a need for more information. This entails gathering vast and diverse information as to where bio-science activities occur and linking that information with data about criminal networks and smuggling operations from police and customs files. Identification of an anomaly should provoke follow-on inquiry, either by requesting clarification from a relevant State, by assigning a “task force” to gather more facts, or by authorizing an investigation.

20. Complete reliance on exclusively domestic law enforcement to prevent bio-violence threats would leave unacceptable holes. A global system for preventing bio-violence must have authority to investigate suspicious activity in order to propound confidence in the system’s worldwide efficacy. Every State should cooperate with international efforts to gather and analyze data as are deemed necessary to help detect and interdict covert bio-violence preparations.

21. Law enforcement investigations must be distinguished from arms control verification inspections. The criteria for such investigations must be promulgated by an international body that is responsible for bio-violence prevention policies. Investigations should be rare and must respect the legitimate pursuit of bio-science and must be coordinated with policies for supervising bio-research that might have dangerous implications.

22. To learn how life works is to learn how it is threatened and extinguished. Bio-science cannot produce cures for disease without, simultaneously, recognizing the disease’s capabilities, its vulnerabilities, and our own. The beneficent applications of bio-science are intertwined with their malevolent implications and cannot be disentangled at the level of fundamental science. This is especially problematic because scientific progress inevitably outpaces the incremental growth of law.

23. Many bio-defense projects could generate an offensive capability. The dual-use problem makes it very difficult to draw a clear line between legitimate and illicit research; it is often only a matter of intent whether an experiment is offensive or defensive.
24. Policies to address emerging bio-science risks – policies that complement denial and law enforcement policies – must recognize that scientific progress will proceed regardless of legal norms or constraints, and no nation that has capabilities and political will to develop vaccines and other protective measures against bio-attack will tolerate internationally-imposed constraints on those defensive pursuits. Moreover, the extreme expense of monitoring bio-science research in order to distinguish peaceful purposes from hostile purposes must be weighed against the low likelihood of complete and accurate determinations. Therefore, implementation of arms control transparency policies is inappropriate.

25. Translucency refers to a set of policies that are designed to overcome risks associated with opacity. The heart of these policies is to generate an information flow that might enable detection of wrongful activity as well as to deter easy pursuit of bio-violence. Translucency policies are built on the following presumptions: bio-research involving listed bio-weapons agents, posing a unique threat of weapons application or designed for military applications, must not be performed in absolute secrecy; and dispersal of bio-agents, or preparations to do so, for the purpose of harming living things is prohibited unless internationally sanctioned.

26. The central reason for prohibiting secrecy is to enable accountability: someone would always be able to trace research activity back to its source. Secrecy in biodefense programs raises suspicions and could promote a race for offensive capabilities under cover of defense. Prohibiting secrecy raises confidence that bio-research activities are not undertaken to advance bio-violence. And prohibiting secrecy has deterrent value especially for national bio-defense programs as the challenge of keeping wrongful intentions secret would escalate as would the implications of trying to do so. Accordingly, no bio-research should be black-box.

27. The central requirement with regard to dispersal or bio-agents or preparations for doing so is to shift the locus of decision-making from national to international authorities. For activities that directly engage the BWC prohibition against weaponization, the standards should be global and the decider of where to draw the line should be international. Accordingly, weapons-simulations programs/experiments must be reported internationally; conduct of weapons-simulation programs without disclosure is prohibited.

E.

28. Preventing bio-violence is where the right to health and the separate right to security intersect. It is an avowal of a collective (humanity) right as the foundation for a global administration that integrates promotion of bio-science and public health with security-based responsibilities. Humanity is entitled to every State’s commitment and best effort to implement prevention policies. This right demarcates, perhaps more explicitly than ever, a unity of human purpose transcending boundaries of geography and ethnicity even as it compels finely-tuned governance modalities for our most profound scientific pursuits.

29. It is illegitimate to compel global pursuit of policies for preventing bio-violence in isolation from the far larger pursuit of policies to combat pandemic disease. The global covenant for preventing bio-violence recognizes the human species’ manifold and highly divergent disease threats. Preventing bio-violence is important but it is a facet of a larger
policy agenda that elevates health as a security priority and compels efforts to address global health disparities. Accordingly, each State is obligated, according to its capabilities, to cooperate in the detection, mitigation, and containment of disease; from all States collectively is the obligation to develop legal mechanisms to facilitate international flows of research, assistance and cooperation. Standards of State compliance with bio-violence prevention policies must be fair and sensitive to widely disparate capacities.

30. Scarce public health resources must be allocated for all diseases, proportional to the level of risk and sensitive to gaping differences of capacity. Risks of bio-violence must be assessed along with risks of natural disease but with one important caveat: the assessment of potential harms of bio-violence must include the likely consequence of incomparable levels of panic and political instability. Thus, resource disparities must not excuse disdain for or inattention to reasonable measures to prevent diversion or wrongful use of pathogens.

31. Promotion of bio-science is fundamental to the advance of human well-being, development and security. The Millennium Development Goals call for the application of science and technology for development and emphasize the importance of collective efforts in this regard. There must be a strong presumption against restrictions on the distribution of scientific knowledge, against trade restraints on the distribution of pharmaceuticals and other biological products, and against constraints on the movement of bio-scientists. Yet, because of the risks associated with bio-violence, bio-science must be advanced along with a commitment to protect against its hostile applications. Development funding in bio-science activities should be contingent on implementation of security controls; correspondingly, pro-active implementation of specific controls and cooperation with relevant international organizations should encourage developmental support. With opportunities and encouragement necessarily comes responsibility -- no matter how great the need, no one should be able to obtain benefits by ignoring risks.

32. Among such assistance and resources, attention should be given to international efforts for:
   - Promoting bio-science education and centers of excellence in bio-science
   - Strengthening universities, research institutions, academies of science and other scientific networks
   - Establishment of joint research and development program for vaccines and other capabilities to protect against disease with special focus on HIV/AIDS, TB, and malaria;
   - Building of public health infrastructure and capacity, and development of preparedness and disease outbreak response assessment capabilities;
   - Creating and sustaining disease monitoring, notification, and surveillance systems;
   - Development of public health communication systems that are connected with global communication systems; and
   - Raising awareness and understanding of disease, whether deliberate or natural, through *inter alia* strengthening the capacity of civil society.

33. The global authoritative structure with regard to bio-violence prevention should comprise three bodies within the United Nations. The *United Nations Committee on Bio-Science* (UNCBS) would be responsible for assisting developing countries in using bio-
science and bio-technology for development. The United Nations Office of Bio-Violence Prevention (UNOBVP) focuses on assisting Member States to implement measures against bio-violence and to facilitate concerted action among States and United Nations bodies against bio-violence. The United Nations Commission on Bio-Violence (UNCBV) will decide on a long-term bio-violence prevention strategy and facilitate an institutional and systematic inter-connection among the network of assistance and expert bodies as might be relevant.

34. Building confidence that State bio-defense programs are, in fact, not bio-terrorism preparations by disclosing selective information about such programs.

35. Encouraging the global spread of legitimate bio-research, pharmaceutical production and public health capabilities by fashioning linkages of these capabilities with implementation of biosecurity measures.

36. Developing standards to measure State compliance with bio-terrorism prevention policies that are fair and sensitive to widely disparate capacities and, where appropriate, to facilitate compliance or initiate enforcement efforts.

1 Ancient custom condemns the use of poison or poisoned weapons in war or the use of weapons causing unnecessary suffering. Among prohibitions in many civilizations were the poisoning of food and wells and the use of poison weapons. The Greeks and Romans condemned the use of poison in war as a violation of *ius gentium*, the law of nations. Poisons and other weapons considered inhumane were forbidden by the Manu Law of India about 500 B.C. and by the Saracens a thousand years later. Leonard A. Cole, *The Eleventh Plague: The Politics of Biological and Chemical Warfare*. 2

3 For the most recent and most thorough discussion of current bio-weapons programs and non-State capabilities for committing bio-terrorism, see Dr. Milton Leitenberg, *Assessing The Biological Weapons and Bioterrorism Threat*, Dec. 2005.

5 “The risk should be calculated based both upon the probability and the foreseeable consequences of the agent’s use.” Jennifer Gaudioso, *A Conceptual Framework for Biosecurity Levels*, SANDIA NATIONAL LABORATORIES (SAND 2004-0759C) (2004) [4]  Risk assessment of a biological agent for use as a bioweapon should include the following factors: “Availability (number of facilities that house the pathogen or toxin); Ease of amplification (rate of growth, nature of growth media, level of technical equipment and expertise required, etc.); Ease of processing (including ease of aerosolization and increased inhalation characteristics); Environmental hardness (viability in a broad range of temperatures, hydration levels, light sensitivity, etc.); Lack of availability of countermeasures/immunity (pharmacotherapies or prophylaxis); Ability to be camouflaged as an endemic or common disease.” Reynolds M. Salerno & Daniel P. Estes, *Biosecurity: Protecting High Consequence Pathogens and Toxins Against Theft and Diversion*, SANDIA NATIONAL LABORATORIES (SAND NO. 2003-4274P) (2003).
Scientists at Cornell recently developed a new technique that could make both detection and tracking of pathogens possible. They were able to create small segments of inactive DNA that would bind to the DNA of particular pathogens. Taking a sample of several different bacteria and viruses mixed together (for example, the researchers successfully identified the various strains of pathogen in different combinations of E. coli, anthrax, tularemia, ebola, and SARS), the scientists introduced the synthetic DNA “barcodes”. The scientists then introduced nano-probes with different combinations of dye molecules that would bind to the DNA of particular pathogens. Once disseminated, the agent must be capable of establishing field dosages that are infective or toxic over a particular area. It must also be relatively easy to produce from readily available precursor compounds or from naturally occurring or genetically modified organisms.

The WHO focuses on the, “principle biological agents known to have entered the process of weaponization during the Cold War, in other words, agents which have been used in the past;” agents which are known to been weaponized or stockpiled; “considerations regarding non-state entities; and agents condemned under the BWC. The list is available at http://www.who.int/csr/resources/publications/discrimination/en/Id.pdf and see also Yougen Li, Yen Thi Hong Cu & Dan Luo, “Multiplexed detection of pathogen DNA with DNA-based fluorescence nanobarcodes”, in Nature Biotechnology, vol 23, number 7, July 2005.

12 Guidelines for the Establishment and Operation of Collections of Cultures of Microorganisms, 1st edition 1990, 2nd edition 1999) available via the World Data Centre for Microorganisms (WDCM) web site (http://wdcm.nig.ac.jp/). These guidelines discuss the importance of preserving collections of cultures and microorganisms and stress the need to share and document the information. Safety and Quality Standards, para. 16.2 states: "Particular attention needs to be given to the containment and security aspects of strains which are 6 [F]or deliberate use (or threats of use) for chemical and biological agents, a spectrum of threat can be envisaged that ranges between those relative insignificance at one end, mass destruction of life and casualties at the other. Where along this spectrum a particular biological or chemical menace is situated will be determined by the characteristics of the agent and the way it is used, and by the vulnerability of the threatened population, reflecting such factors as the health status and degree of preparedness of that population.” Public Health Response to Biological and Chemical Weapons: WHO Guidance, 2nd ed. of Health Aspects of Chemical and Biological Weapons: Report of a WHO Group of Consultants. 1st ed. 1970; 2nd edition 2004.

7 Id. at 25-26. According to the WHO Guidance:

An agent of concern would be one that is stable enough to resist degradation during handling and storage, and during the energy-transfer processes, that will, in most scenarios, be involved in disseminating it on its targets. Once disseminated, the agent must be capable of establishing field dosages that are infective or toxic over a particular area. It must also be relatively easy to produce from readily available precursor compounds or from naturally occurring or genetically modified organisms. The WHO focuses on the, “principle biological agents known to have entered the process of weaponization during the Cold War, in other words, agents which have been used in the past;” agents which are known to been weaponized or stockpiled; “considerations regarding non-state entities; and agents condemned under the BWC.

8 The list is available at http://www.oie.int/eng/maladies/en_classification.htm Pathogens are grouped into four levels of organisms with increasing hazards to human health, but the list does not rank the diseases in any order nor specify their relative risks of human infection or for weaponization. Some of the factors that should be considered when determining a specific pathogen’s level of risk are: “the epidemiological background of the organism and also such attributes of the organism as infectivity for humans, stability in the environment, ability to infect by different routes, and susceptibility to specific treatments or prophylaxis.” 


9 Id. at 18-19.


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13 Guidelines for the Establishment and Operation of Collections of Cultures of Microorganisms, 1st edition 1990, 2nd edition 1999) available via the World Data Centre for Microorganisms (WDCM) web site (http://wdcm.nig.ac.jp/). These guidelines discuss the importance of preserving collections of cultures and microorganisms and stress the need to share and document the information. Safety and Quality Standards, para. 16.2 states: "Particular attention needs to be given to the containment and security aspects of strains which are
potentially harmful to man, animals or crops.” [http://wdcm.nig.ac.jp/biowarfare.html](http://wdcm.nig.ac.jp/biowarfare.html) The WFCC performs an important function of keeping its members aware of national and international legislation concerning culture collections. Its Committee on Postal, Quarantine and Safety Regulations recommends increased vigilance with respect to dangerous pathogens. Organisms listed in the World Data Centre for Microorganisms (WDCM) are available subject to the provision of relevant permits and licenses and released only to bona fide users in compliance with national and international laws.


15 WHO22 - [http://www.who.int/tdr/publications/publications/pdf/qlp-handbook.pdf](http://www.who.int/tdr/publications/publications/pdf/qlp-handbook.pdf) This Handbook is designed to aid countries to raise their laboratories to GLP status by providing rules to ensure the quality, integrity, and reliability of study data from non-clinical safety studies. Based on the Organisation for Economic Cooperation and Development (OECD) principles of GLP, it provides the necessary technical information for implementing GLP programs to laboratories and their trainers in disease-endemic countries. The Handbook reviews the need for quality standards in drug research and development and provides a history of GLP with chapters covering: GLP training, the stepwise introduction of GLP, and the OECD principles of GLP and compliance monitoring.

16 These facilities serve as information hubs that standardize laboratory practices and assure the use of appropriate technology, and they offer capabilities for collaborative research, training, policy planning, and outreach to other facilities. Laboratories must provide data to be so designated and are subject to inspections to verify their compliance with guidelines. These are perhaps the only systems to directly link the operation of bio-research facilities internationally and to enable oversight of State and private bio-activities.

17 The IFBLS recently issued a report to its members explaining the more popular approaches related to quality standardization, including the ISO 9000 system for standardization in medical laboratories. The IFBLS is affiliated with a number of prominent international organizations. For example, it has close ties with the Active Broad Interest Member of NCCLS, which is a globally recognized, voluntary consensus standards-developing organization that develops and disseminates guidelines and best practices for medical testing.


19 Reynolds M. Salerno & Daniel P. Estes, *Biosecurity: Protecting High Consequence Pathogens and Toxins Against Theft and Diversion*, SANDIA NATIONAL LABORATORIES (SAND NO. 2003-4274P) (2003). [6-7]; See also Centers for Disease Control and Prevention, *Laboratory security and emergency response guidance for laboratories working with select agents*, MORBIDITY AND MORTALITY WEEKLY REPORT 2002;51 (No. RR-19) [3] (stating that threat assessment “identifies and evaluates each threat on the basis of different factors (e.g., the capability and intent to attack an asset, the likelihood of a successful attack, and the attack’s probable lethality).” Id.)


21 Centers for Disease Control and Prevention, *Laboratory security and emergency response guidance for laboratories working with select agents*, MORBIDITY AND MORTALITY WEEKLY REPORT 2002;51 (No. RR-19) [3]

22 Jonathan B. Tucker, *Biosecurity: Limiting Terrorist Access to Deadly Pathogens*, UNITED STATES INSTITUTE OF PEACE (2003). [28]; See also Reynolds M. Salerno & Daniel P. Estes, *Biosecurity: Protecting High Consequence Pathogens and Toxins Against Theft and Diversion*, SANDIA NATIONAL LABORATORIES (SAND NO. 2003-4274P) (2003). [7] (noting that diversion or theft of dangerous biological materials or equipment is likely to occur either via an insider with access to the materials or by an outsider “who would attempt to steal a biological agent covertly. This type of adversary would likely avoid detection and abort their diversion attempt if they thought they would be caught.” Id.)

23 This is, of course, the reason for UNSCR 1540. However, that resolution lacks sufficient detail to enable anyone to assess whether State legislation is sufficient or not. See
UNSCR 1540’s immediate provocation was the discovery of Dr. Khan’s global network for distributing nuclear weapons capabilities, including passage of technology, designs, and components to Iran, North Korea, and Libya. When Colonel Muammar Qadhafi turned his nuclear program over to the US, some of the uranium was found to be of North Korean origin, traded in return for hard currency through Dr. Khan’s network. Dr. Khan also toured sub-Saharan Africa between 1998 and 2002, presumably looking to trade nuclear secrets in return for uranium for his nuclear program. Notably, many of the components of Dr. Khan’s enterprise came from suppliers who claimed that their activities – e.g. furnishing highly sophisticated nuclear technology to Pakistan – were not prohibited. Although this self-serving claim can be disputed, S. Res. 1540 seeks to ensure that henceforth no one can hide behind the defense that relevant laws are so vague that they reasonably thought that they were behaving legally. According to Mr. Jenie of Indonesia: “Illegal networks exist that can deliver nuclear materials and technology that can be used to produce weapons. In dealing with these potentially dangerous situations, we are hampered by the lack of any legal framework that would effectively thwart the efforts of non-State actors, in particular terrorists, to acquire and illegally transfer nuclear and other WMD materials. … [T]here are no internationally acceptable provisions to penalize illegal proliferation activities by individuals or non-State actors.”

Broad bases of jurisdiction appear in many of the treaties on international terrorism that are currently in force. See Maritime Convention, Art. 6; Maritime Protocol, Art. 3 & 5; Tokyo Convention, Art. 4; Internationally Protected Persons Convention, Art. 3; Hostages Convention, Art. 5; Terror Bombing Convention, Art. 6; Nuclear Material Protection Convention, Art. 8; and the Terror Financing Convention, Art. 7. See generally M.C. Bassiouni, INTERNATIONAL TERRORISM: MULTILATERAL CONVENTIONS 305 (2001). Mechanisms to avoid jurisdictional problems and situations such as those involved in the Bombing of Pan Am 103 are now readily understood in international criminal law. See Concerning Questions of Interpretation and Application of the 1971 Montreal Convention Arising from the Aerial Incident at Lockerbie (Libya v. U.S.), 1992 I.C.J. 4, 121-122


- Demonstrate how to render a vaccine ineffective
- Confer resistance to antibiotics or antiviral agents
- Enhance the virulence of a pathogen or render a nonpathogen virulent
- Increase the transmissibility of a pathogen
- Alter the host range of a pathogen
- Enable evasion of diagnosis or detection methods
- Enable weaponization of a biological agent or toxin
A longer list was generated by the CISSM Project on Dangerous Pathogens:

<table>
<thead>
<tr>
<th>Extremely Dangerous Activities (EDA):</th>
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<tbody>
<tr>
<td>• Work with eradicated agent*</td>
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<tr>
<td>• Work with agent assigned as BSL-4/ABSL-4</td>
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<tr>
<td>• De novo synthesis of above</td>
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<tr>
<td>• Expanding host range of agent to new host (in humans, other animals and plants) or changing the tissue range of a listed agent**</td>
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<tr>
<td>• Construction of antibiotic- or vaccine-resistant listed agent</td>
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<tr>
<th>Moderately Dangerous Activities (MDA):</th>
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<tbody>
<tr>
<td>• Work with a newly discovered agent preliminarily assigned as BSL-3/ABSL-3***</td>
</tr>
<tr>
<td>• Increasing virulence of listed agent or related agent</td>
</tr>
<tr>
<td>• Insertion of host genes into listed agent or related agent</td>
</tr>
<tr>
<td>• Increasing transmissibility or environmental stability of listed agent or related agent</td>
</tr>
<tr>
<td>• Powder or aerosol production of listed agent or related agent</td>
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<tr>
<td>• Powder or aerosol dispersal of listed agent or related agent</td>
</tr>
<tr>
<td>• De novo synthesis of listed agent or related agent</td>
</tr>
<tr>
<td>• Construction of antibiotic- or vaccine-resistant related agent</td>
</tr>
<tr>
<td>• Genome transfer, genome replacement, or cellular reconstitution of listed agent or related agent</td>
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</table>

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<tr>
<th>Potentially Dangerous Activities (PDA):</th>
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<tr>
<td>• Work with listed agent—or exempt avirulent, attenuated, or vaccine strain of a listed agent — not covered by EDA/MDA</td>
</tr>
<tr>
<td>• Increasing virulence of non-listed agent</td>
</tr>
<tr>
<td>• Increasing transmissibility or environmental stability of non-listed agent</td>
</tr>
<tr>
<td>• Powder or aerosol production of non-listed agent</td>
</tr>
<tr>
<td>• Powder or aerosol dispersal of non-listed agent</td>
</tr>
<tr>
<td>• De novo synthesis of non-listed agent</td>
</tr>
<tr>
<td>• Genome transfer, genome replacement, or cellular reconstitution of non-listed agent</td>
</tr>
</tbody>
</table>

Similar issue areas and questions have been suggested by the British Royal Society for assessing dual-use research. See Royal Society, *The Role Of Scientific Codes In Preventing The Misuse Of Scientific Research*, RS policy document 03/05, May 2005.

According to the UMD Pathogens Project: Knowledge of fundamental life processes has progressed to the point that extensive human intervention in the course of natural evolution has apparently become feasible, not only to determine particular outcomes but to redirect the process itself. One can credibly imagine the eradication of a number of known infectious diseases. One can also credibly imagine the deliberate or inadvertent creation of new pathogens dramatically more dangerous than those that have naturally evolved. One can similarly imagine both therapeutic and destructive applications affecting basic features of cognitive, emotional, and reproductive activity. Hundreds of millions of lives might be enhanced, salvaged, manipulated, degraded, or terminated depending on how the same basic knowledge is applied. Little of that potential has yet been accomplished but none of it can be dismissed as fantasy. … As a result, the human species is relentlessly acquiring power far in excess of its vision and this is thereby posing monumental problems of prudential judgment -- problems that society is not yet conceptually or institutionally equipped to handle.

According to the UMD Pathogens Project: The relevant biomedical research community is very extensive and globally distributed. More than a million scientific articles are published every year and seminal results are generated in all parts of the world. Information flows rapidly among leading-edge scientists and knowledge of fundamental developments also transfers rapidly to those in training. Given that situation, it seems obvious that adequate measures of protection against the misuse of biological research would have to be devised globally, not just for academic researchers but also for those working in commercial and government labs.

Some Thoughts on Biodefense Research.

In a program code-named Clear Vision, the Central Intelligence Agency built and tested a model of a Soviet-designed germ bomb that agency officials feared was being sold on the international market. Hundreds of bomblets were made, although they lacked a fuse that would make it a working bomb. A related project developed models to predict agent distribution and potency as a function of the dispersal method, variations in the source over time, the agent type, the amount of agent and its state (dry or wet), size distribution, environmental conditions, etc. - data that appear to have considerably greater offensive than defensive potential. Infectious agents as well as simulants are to be used. At a Senate hearing in May 1989, Colonel David Huxsoll, Commander, US Army Medical Research Institute for Infectious Diseases, testified: “To create a weapon…the issues of stability, dissemination and weapons delivery systems would have to be addressed. According to Germs, a book by the New York Times reporters who uncovered the project, the bomblets were filled with simulant and tested both for the way they would fall after release from a warhead and for their dissemination characteristics. To test dissemination of the BW agent simulant, the bomblet must have been detonated, if not via its own fuse, then by some external means.

The program produced anthrax arguably in amounts unjustifiable for peaceful purposes. Whether it was that anthrax that was lethally used in 2001 is unclear.

The Naval Research Laboratory (NRL) has a program “focused on identifying and characterizing the degradative potential of products from naturally-occurring microorganisms”. NRL takes natural microbes and creates genetically engineered organisms with “focused degradative capabilities”. These include microbes designed to destroy plastics, particularly polyurethane, which is used as coatings for aircraft. And Oak Ridge National Laboratory in Tennessee, working with the Center for Environmental Biotechnology of the University of Tennessee, has conducted field tests of a genetically engineered bioremediation bacteria. For GMO microbe tests, Oak Ridge has constructed unique high-security field lysimetry facility (pictured), a series of twenty enclosed containers with a total capacity of over 250 square meters of soil. According to NRL, “The potential for clandestine employment of these non-lethal weapon systems, particularly since their effects in many cases may closely mimic natural processes, gives an adversary an added advantage of deniability”. Such technology would be very useful for offensive GAMAs, because it would prevent organism spread to unintended targets, impede use by an enemy, facilitate cleanup, and help prevent a ‘boomerang effect’ of the organism inadvertently impacting friendly forces by surviving beyond its intended mission.
Federal outlays for research and development on biodefense jumped sixfold in one year, from $291-million in 2002 to $1.75-billion in 2003, and similarly large appropriations were made in 2004 and have been proposed in the administration's budget request for 2005.

Prepared Statement of the Honorable Hans Mark, Director of defense research and engineering.

- Characterize molecular biology and physiology of biological threat agents;
- Investigate the pathogenesis and immunology of the disease;
- Determine the mechanism of action of the threat agent through modeling;
- Identify new medical biological defense products by understanding their interaction with and mechanisms of action against BW agents;
- Establish safety and efficacy data for new medical bio defense products; and
- Establish the validity of new medical bio defense products against battlefield use.

The results of such research are expected to facilitate pursuit of a variety of critical goals - e.g., the development of rapid diagnostic methods for the most likely biological weapons, the development of new or improved antibiotics, the development of antiviral therapies for smallpox and Ebola virus, and the development of new vaccines for smallpox and anthrax.

Prepared Statement of William F. Raub PHD, Deputy Assistant Secretary of Science and Policy for the Department of Health and Human Services. Projects in the current U.S. biodefense program include investigation of the pathogenesis and physiology of bio-threat agents, modeling the mechanism of threat agents, simulation of pathogen releases, analysis of agent’s transmissibility including tissue culture models, and identification of new medical defense products by understanding their interaction with BW agents. Of course, the very same techniques and frequently using the genomes of the identical pathogens that were at one time or another in recent decades seen as biological weapons are currently used in defense research. The Chemical and Biological Defense program, recipient of over $160 million, is studying how advances in technology, specifically genetic engineering and recombinant DNA, can be used to develop countermeasures to BW threat agents. Prepared Statement of the Honorable Hans Mark, Director of defense research and engineering.

NBACC aims to achieve efficient interagency and private sector cooperation with a structure that integrates facilities and technical expertise in biodefense and involves Plum Island Animal Disease Center, national and DHS laboratories, universities, the private sector and other government agencies. Biodefense characterization, bioforensics and agricultural security are the key programmatic thrusts of NBACC that are executed through these five research and operations centers: Biothreat Assessment Support Center; Biodefense Knowledge Center; Bioforensics Analysis Center; Bio- Countermeasures Testing and Evaluation Center; and the Plum Island Animal Disease Center.

UMD Dangerous Pathogens Project: “the risk-benefit assessment of dual-use biological research would apply to all relevant research, irrespective of whether it is to be carried out in a government, industry or academic laboratory. In addition, the relevant review body would be required to consider certain specified issue areas as part of its deliberations and to document the discussion of these issues as well as its overall risk-benefit assessment in its meeting minutes. A record of the review judgments made would be preserved at all levels and under the most advanced arrangement the international review body would periodically organize efforts to harmonize the judgments made by separate national and local review bodies using project case histories as the basis for discussion.” … “As these criteria show, meaningful peer review would require the disclosure to the appropriate review body of detailed information necessary to weigh the risks and benefits of a proposed experiment. In an advanced arrangement, the international review body would have the primary right to information directly relevant to projects falling under its jurisdiction. In particular, information demonstrating extreme risk to the human species as a whole would have to be disclosed, as would information relating to the defining determinants of risk.”

A relevant process was used by the US NAS to handle the dissemination of sensitive portions of its 2002 study on agricultural bioterrorism. In response to security concerns from the US Department of Agriculture, which funded the study, NAS officials developed guidelines for the types of individuals who could be given access to the controlled information. Anyone interested had to submit a written request and be interviewed by NAS staff before
Individual or even group rights operate somewhat distinctly from rights that operate across the entire span of the human species. Human (individual) rights espouse either a limit on what one a government can do to people (a negative right) or an obligation for that government to provide or enable something for people (a positive right). Inherently, such rights pose a juxtaposition between the beneficiary(s) and the State that must obligate the right; at least in aspiration, such rights should be enforceable by an intended beneficiary against the obligated State. This juxtaposition is not particularly relevant to rights that apply humanity-wide. In these contexts, the point is not to legally enforce an obligation that the State owes to a person(s) – it is rather to specify multiple responsibilities and to deny safe haven to a State that might ignore its responsibilities.

This operational difference can be illustrated by focusing on the right to health. An individual right to health (as manifest, for example, by Article 25 of the Universal Declaration on Human Rights) focuses on individualized medical care and is thought to embrace basic provisions of emergency health care as necessary to save lives, including the treatment of prevalent diseases, the provision of essential drugs, and safeguards against serious environmental health threats. “Thus, the right to health remains mired in a curative or clinical model of health.” Espousing a collective right to health, by contrast, means to promote conditions that reduce disease threats, e.g. buttressing sustainable health infrastructures including disease surveillance and public health epidemiological programs. “Whereas medicine focuses primarily on individual curative treatments in clinical settings, public health actions protect and promote the health of entire populations by using multi-disciplinary interventions to address the underlying determinants of health and disease.”

The World Health Organization (WHO) is already responsible for designating dangerous pathogens and for specifying their handling and packaging procedures. If there is to be a marking system for those pathogens and a database to track their movement, the WHO would be an obvious body to undertake those tasks. Both the WHO and the animal health organization (Office International des Epizooties (OIE)) specify elaborate standards for authorized collaborating or reference laboratories. The International Federation of Biomedical Laboratory Science (IFBLS) helps train medical and bio-science personnel and promotes the ISO standards applicable to laboratories. The International Labor Office (ILO) establishes workplace safety standards; its responsibilities could extend to laboratory personnel training and certification in connection with enhancing bio-security. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) recommends greater harmonization of technical requirements for new medicines while maintaining safeguards on quality, safety and efficacy to protect public health. The World Customs Organization (WCO) is developing modalities for tracking the contents of shipments from their original source, through border controls, to their final destination; the application of these modalities to pathogens is clearly on the horizon. Numerous organizations including the International Maritime Organization (IMO) and the Universal Postal Union (UPU) implement and oversee standards for packaging and labeling pathogens in transport. The International Center for Genetic Engineering & Biotechnology (ICGEB) offers consultation for scientific programs in developing nations and disseminates a database of bio-safety studies. International development and financing organizations (e.g. IMF and the World Bank) have a central role in the global bargain for bio-security. As has been noted, the bio-research and pharmaceutical sectors are spreading through the developing world, opening opportunities for improvements in science and public health. There is every reason to suggest linking this progression to fulfillment of bio-security obligations: development funding in bio-science activities should be contingent on implementation of security controls; correspondingly, a State’s (or other entity’s) pro-active implementation of specific controls and cooperation with relevant international organizations should encourage developmental support. This progressive linkage is the tangible core of the bio-security bargain.