Soft Regulatory Mechanisms and Open-source Bioethics to Counter Biothreat Proliferation

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Abstract

This article explores the relative merits of soft regulatory mechanisms (SRM), generally known as soft power diplomacy, as a catalytic conduit to promote global awareness of bioethical issues as it relates to biosecurity and dual-use research of concern (DURC). Based on a 2-year international panel workshop-study evaluating the sociocultural and bioethical dimensions of future biosecurity, this article provides a conceptual outline for implementation of alternatives aimed at fostering active engagement of international stakeholders involved in the formulation and execution of policy and law related to biosecurity, and investments in life sciences research and technology development. Based on the demonstrated effectiveness of soft power diplomacy models implemented in the national and international arena in public health security, environmental protection, and biological threat reduction programs, the authors provide an outline for a conceptual architecture for a global bioethical network aimed at increasing awareness among the stakeholder communities of the risks posed by the next generation of biothreats, emerging new diseases, and DURC in the age of bioterrorism.

Introduction

Much of the current focus in biodefense, aimed at countering current and emerging biological threats, has been interdisciplinary in scope, drawn mostly from the foundational ethical guidelines for medicine, science, public health, law, the environment, war, and international relations. As a result, biodefense and counter-bioterrorism programs at national and international levels have sought to employ conventional regulatory frameworks by merging a collection of concepts and guidelines implemented as “hard regulations,” but without systematically addressing the unique challenges posed by biodefense and biological threats. Technical and policy experts concur that hard regulations are likely to be counterproductive in the long run, when the academic research and private enterprise business models thrive on the basic principle of freedom to pursue scientific research and free exchange of information among the community of researchers and biotechnology business entrepreneurs (Roland, 2007).

Public policymakers in government and multilateral agencies faced with challenging tasks involving environmental protection, national security, economic policy, healthcare, and labor laws are beginning to explore a range of options that include command-and-control type regulations and others involving participatory instruments and working with stakeholders to change behavior (Gaudioso & Salerno, 2004; Gunningham & Sinclair, 1998). For example, comparative risk assessment is increasingly used as a decision-making tool in the environmental and public health policy decision-making process involving the scientific community, public policymakers, and public stakeholder communities (Alm & Rao, 1994). The U.S. National Research Council employed a biological risk assessment paradigm to assess the operational safety of advanced emerging pathogen disease research laboratories (NRC, 2010a), or the maximum credibility event-based environmental consequence analysis to assess safety of high biocontainment laboratories (NRC, 2010b). From a public policy standpoint, some experts and professional organizations have suggested the use of the public health model proposed by Buchanan (2000), where individual interests are subordinated to the interests of the common good of society as the guiding framework for what might constitute a “soft regulation” to biodefense bioethics and a basis for countering biological proliferation threats.

Guzman and Meyer (2011) have proposed a formulation for international soft law on international common law to form the basis for international tribunals towards non-binding interpretations of binding legal rules. As a result, legal consequences flow from a range of nonbinding international instruments similar to expert committee recommendations and advisories and guidelines developed by regulatory agencies in the domestic setting that do not have enforcement powers or legal consequences due to noncompliance. Legal experts have opined that the quasi-legal characteristic of international soft law will be attractive to state parties engaged in a multilateral forum on a regional or international issue.

Application of soft regulations is a well-established mechanism in international diplomacy, such as in regional and global multilateral fora aimed at global health protection (Magnusson, 2007; Sutton, 2009; WHO, 2003), prevention and elimination of chemical and biological weapons of mass destruction (Lee, 2004), labor laws (Borghis et al., 2003; Kuruvilla & Verma, 2006), environmental protection (Alm & Rao, 1994; Koutalakis et al., 2010), and human rights (Andorno, 2009, 2007; Hillgenberg, 1999).
Using illustrative examples from these well-established international initiatives, this article outlines the basic framework for a soft regulatory mechanism as part of regional or global efforts to coordinate the pursuit of scientific investigations and to manage biological threat proliferation.

At the conclusion of the 2006 Biological Weapons Convention (BWC) meeting, titled “Sixth Review Conference of the State Parties to the Biological Weapons Convention,” held in Geneva, it was concluded that national implementation would remain the biggest challenge during the 2007-2010 Intersessional program, which focused on regional cooperation; biosafety and biosecurity; oversight measures for biological research; and increased awareness, educational measures, and international cooperation in biological science and technology. BWC review conferences implement a quasi-regulatory framework to meet the goal of the treaty, which is to promote the development of the peaceful uses of biological agents and toxins. The confidence-building measures outlined in these sessions are supposed to provide practical steps to increase the level of participation at the national level and of various stakeholders in the biological research and the biotechnology industry communities.

Exploring confidence-building measures in the context of the BWC might offer attractive alternatives in the formulation of advisories and guidelines as policies related to ethical, political and social issues have grown in tandem with the spectacular advancement in biological research and biotechnology. Evidently, scientific progress has outpaced science policy formulation, particularly regarding contentious bioethical issues. A growing concern over DURC among scientific researchers and security experts has provided sufficient impetus to explore alternate policies aimed at soft regulatory options (Sutton, 2009). Current mandates or treaty frameworks—be they at the national or international levels—are nowhere closer to addressing the intricacies of the policy challenges posed by advanced biotechnology; therefore, conventional regulatory mechanisms are not part of a long-term solution.

Background

In one of the first conferences of its kind in Europe, a panel of experts explored the ethical implications of scientific research on bioweapons and prevention of bioterrorism (EC, 2004). More recently, the NATO Advanced Research Workshop (ARW), “Ethics, Morality and the Law: Managing Bioterrorism Threats,” convened an international panel of experts to discuss topics related to bioddefense and bioterrorism. This has the potential to have a seminal impact on a wide range of national and regional security programs and science-policy areas covering life sciences research and development, dual-use research, health security, and managing bioterrorism threats (DTRA, 2010).

In both events, participating experts were specifically tasked to: a) identify mutually contrasting and overlapping viewpoints on the interdisciplinary areas related to bioethics, life sciences research, jurisprudence, and bioterrorism preparedness and response initiatives; b) create a conceptual framework for extended discussions and interactions among the domain experts and key stakeholders; and c) recommend action plans for a systematic process to begin sustained engagements among key stakeholders at national and international levels.

The discussions during the 3-day ARW covered an array of views and positions regarding contemporary bioethics and potential implications on education and awareness, advanced biological research and development, national and regional security, and legal and moral implications when managing bioterrorism response (Magnusson, 2007; Rao, 2010a).

A key observation from the ARW deliberations was that better understanding and delineation of the public policy domains is the first point where bioethical issues directly juxtapose national security challenges. Relevant topics for further consideration were improved awareness and education, opportunities towards manpower training and harmonization, as well as the implications of bioethical issues involved in life sciences research and biosecurity (Rao, 2010b).

Figure 1 lists topics discussed at the 2010 ARW where bioethics-related issues are likely to overlap with operational challenges associated with the implementation of bioterrorism preparedness and response measures. ARW participants considered these (among other key themes) as the basis for a more detailed review and discussion.

Identification of these overlapping domains was a key milestone at the 2010 ARW. The working group considered these topics as the basis for constructing a sustained engagement aimed at improved awareness and education, review of DURC, and further exploration of policy options towards “soft” regulations and harmonization of best practices.

A Broader Context for Soft Power Diplomacy (SPD)

One of the more common examples used to describe the demonstrable effectiveness of SPD is its application in global communication via broadcasting media. For example, in the aftermath of World War II, when the Cold War had just begun between the U.S. and the Soviet Union, Radio Free Europe and Radio Liberty were created by the United States and the British Broadcasting Corporation (BBC) as conduits to provide more accurate world news to listeners all over the world, particularly to the audience in Eastern Europe, South East Asia, East Asia, Africa, and Latin America. Cultural centers were created all over the world as another conduit to communicate the merits of democracy and a free market society to the common man. A long-term objective was to use these communicated merits to generate admiration and respect for the West. It is interesting to note that SPD tools related to communication were instituted as public diplomacy to alter the behavior of foreign powers by influencing its citizens. The basic as-

The scientific community has embraced the latest technological innovations in communications and information-sharing with the utmost enthusiasm. This is evidenced by a growing number of online versions of peer-review journals, web sites, and portals exclusively devoted to new biology and life sciences research; here, a vast global network of scientists and technical experts can share information on their current research interests, findings, and guidelines for others to experiment and validate. The open forum used by the scientific community fosters transparency, promotes information-sharing, and propels innovation in research and development. Simultaneously, this environment poses serious security issues on what are generally known as DURC. No regulatory mandates oversee and monitor the vast online media currently used by the scientific community, and it is safe to assume that mandated regulations are less likely to modulate individual scientists regarding ethical questions related to DURC and its potential impact on the research institutional safety and national security. Within this context is where employment of SPD options might prove more effective in modulating behavior through voluntary means. There are good examples, albeit from other industry sectors, where use of SPD options has yielded desirable outcomes.

Public diplomacy related to national and international policy on environmental protection and promotion of equity in labor laws and workman compensations has yielded
positive outcomes of global significance. For instance, in global labor governance—in the absence of a formal legal framework—self-regulation, norm setting, and international labor codes provided a policy premise attractively referred to as “voluntaristic initiatives” (Hassel, 2008). Remarkably, the SPD measures to rectify global labor governance did not stem from national governments or from multilateral forums such as the United Nations or the World Trade Organization. Instead, the public diplomacy channeled through mass media and social networking created broader global awareness on issues related to workplace safety and compensation. As a result of increased global public awareness and response by way of consumer boycotts, the private sector adopted more progressive workman compensation programs and invested in improving the quality of workplace conditions, for they could not afford to ignore the collective voice of their consumers (Hassel, 2008). As a result, we now witness a vast number of large, multinational corporations embracing good labor practices and even publicizing these efforts in the marketing of their products. Companies now tout their safe workplace environment, good wages, and best labor practices as part of a corporate culture because it is popular now to be socially responsible.

While one could argue that some sectors within the industry have adopted ethical practices because it is the right thing to do, a compelling argument could be made that it makes a better business case offering or a better economic incentive, or arguably that it is a necessity for companies to meet or exceed the ethical demands of consumers and their special interest groups. SPD in this case could be interpreted as the collective voice of consumers that now has a huge influence on the global marketplace and the international economy.

A broader global acceptance of an environmentally friendly “green policy” is yet another example where SPD measures have made a significant impact on environmental diplomacy when environmental treaty-making systems were deemed less effective (Susskind, 1994). SPD in environmental diplomacy offered self-enforcing options to nation-states without compromising their sovereignty and promoted better coordination among the various institutions involved. NGOs working on environment and global ecosystem protection promoted SPD tools and measures as part of global agreements aimed at environmental sustainability, greater awareness of pollution, and the need for environmental protection. Progress was made possible in this arena by carefully crafted SPD tools and methodologies that were deployed to influence government policymakers and regulators, private and public sectors, academia, and the international media.

**Soft Power Diplomacy to Counter Biological Threats**

It is evident from the preceding section that SPD tools and methodologies have remarkable success in the formulation and implementation of national and international policies related to public health, trade and commerce, and protection of the environment and ecosystem. Human pursuits to understand natural processes through research and discovery are essential aspects of our society, and therefore, SPD tools imparting education and training for aspiring scientists to increase awareness on the dual-use threats and instill code of conduct for responsible behavior may succeed as well.

Existing biological threat-related mandates are mostly hard regulations promulgated either at the national level or a binding requirement under the existing international biological arms control regime. However, during the past 2 decades, policymakers, life sciences researchers, and the biotechnology industrial community have evidenced interest in exploring SPD tools and methodologies in what could be the architecture for future biological engagements covering research and development, global health security, and protection against new and emerging diseases and threats of bioterrorism. Unfortunately, progress in bioengagement architecture remains fragmented due to a divergent stakeholder community and an overall lack of understanding of the potentials of misuse of new frontiers in modern biological research and development.

Bioethics-based SPD provides the enduring quality of higher-order thinking and enhancement of quality of life through self-imposed behavior modification, which is inherently appealing to the research and policy communities. Understanding the moral dimensions of the emerging health and biological systems, and analyzing them according to the bioethical principles and core value system of the community, will drive decision making at the bottom levels, where the practice of science and medicine occurs. SPD will provide the conceptual framework to evaluate a series of competing options and illuminate the inherent recognition that there is no single moral course of action.

Practical application of a bioethics-inspired SPD framework faces fundamental challenges. First, policy analysts and researchers working on SPD in the international arena often cite the sheer complexity of the legal and technical issues involved in domains such as global nonproliferation treaties, international labor laws, and environmental protections that render hard regulations less effective in the long run (Sisson & Marginson, 2001). This would apply to any treaty-based efforts towards nonproliferation of biological weapons given the sheer size, scope, and complexity of modern biological research and the vast and varied applications in the biotechnology domain.

For instance, the 1972 BWC has no provision for enforcement because of the fundamental difficulties with verifiability of treaty compliance. A key problem with the implementation of verification is that the BWC applies not only to sovereign entities but also to private parties as well. Unlike nuclear nonproliferation treaties (and the Anti-Ballistic Missile Treaty [ABM] which involves sovereign nations’ commitment to reduction and eventual elimination through mutually verifiable and implementable protocols),
biological treaty verification covers an extremely vast array of stakeholders involving the private sector, university research laboratories, and contract research facilities in biotechnology R&D and commercial development. A formal inspection regime is bound to be ineffective, and compliance verification is nearly impossible.

Second, bioethics-based SPD approaches are likely to be more effective in the globalized biotechnology research and commercial environment, where business-to-business contacts and networked strategic communication have assumed a prominent role in engaging the stakeholder communities. SPD tools and methodologies are better suited to exploit the evolving social networking and other platforms for communication and information-sharing such as professional societies, disease surveillance and reporting networks, data sharing and reporting systems, and collaborative research programs. SPD tools will greatly benefit the global biotechnology research community and the industry that depends on new biologics-based product development and commercialization. Likewise, global information-sharing on disease prevention and health promotion through the 2005 World Health Organization’s International Health Regulations (IHR) (WHO, 2005) brings the global comity of 194 nations as state parties to voluntarily share disease-specific information through a standard reporting format. The goal to harmonize global rules to categories of infectious disease identification and reporting has inherent appeal as a SPD, where the broader aims are to enhance national, regional, and global public health security.

Finally, bioethics-inspired SPD tools offer more flexible approaches to addressing thorny issues, such as conflicts of interest among stakeholders involved in various aspects of public- and private-funded biotechnology ventures, compared to mandated compliance with national regulations or treaty obligatory requirements. This is basically due to the fundamental differences in the enforcement between SPD and mandatory regulations. Whereas, successful implementation of a mandate is primarily via some form of legal sanction or a form of punishment, SPD methodologies carry no such punishments due to noncompliance. Instead, SPD approaches are primarily driven by ethical and moral implications of advances in biomedical sciences and on value judgments pertaining to code of conduct and responsible behavior in the areas of biological research and biotechnology. SPD tools such as peer-review audits, institutional review boards, best business practices, and institutional collaboration are premised on professional responsibility and practitioners’ voluntary commitment to adhere to institutional-level oversight and the broader ethical and moral questions related to science, medicine, health, life, and the environment.

Education and Training as SPD

Training and educational programs in bioethics and biosecurity as part of university curricula towards advanced degrees in modern biology and biomedical sciences would considerably promote aspiring scientists’ awareness of dual-use threats and recognition of biorisks in their own work and in that of others. Unfortunately, in current university curricula for students, few educational modules exist regarding ethics training on biological and biomedical tracks, and even those few programs treat biosecurity and dual-use issues only superficially. A case-study of bioethics training in the United Kingdom reported that biosecurity-related education received scarce attention from educators, and bioethics course modules reviewed during the study did not adequately address biosecurity and dual-use issues (Revill, 2009).

To a large measure, training in bioethics would serve as the lynchpin in educational programs, bringing up the moral obligations and expectations of responsible behavior on the part of the scientific community regarding the potential security implications of dual-use research (Kuhlau et al., 2008; Selfelid, 2009). Institutions such as Bradford University (Bradford, England) with leading-edge educational programs in bioethics and biosecurity have focused on educational criteria to identify biorisks and obligatory measures on the part of life scientists to take preventative measures. The SPD-based moral obligations offer training modules to: a) prevent bioterrorism; b) engage in responsible activities; c) recognize negative implications of dual-use research; d) avoid submitting for publication study results posing biosecurity risks; e) participate in educational and training programs promoting biorisk awareness and dual-use risks; f) maintain oversight of dangerous pathogens and toxic substances in the laboratory; and g) develop a protocol to deal with suspicious activities of students and laboratory staff. Training modules addressing these core criteria should be available more broadly, both as part of formal educational programs and on-the-job training programs for staff and laboratory operators.

Recognizing the value of dual-use education for scientists, the BTWC Review Conferences have repeatedly identified education, awareness-raising, and ethics training on code of conduct and responsible behavior to prevent potential misuse of biological research (BTWC, 2008). However, no clear guidelines are available to state parties on the nature of educational and training programs, implementation metrics, and performance measures. Given the vast scope and scale of the modern global biological research enterprise, educational programs for national implementation ought to address a much broader range of activities if the goal is to prevent misuse of research and prevent acquisition and use of biological weapons. This is yet another justification to more actively consider SPD-based tools to impart broader awareness through bioethics and biosecurity education and training programs.

Moving Toward a Global Bioethics Network

The conceptual architecture guiding bioethics-inspired SPD will resonate with a) the medical ethics first written in the 18th century by Thomas Percival, which forms the code of ethics in the practice of clinical medicine and the ethical framework in the 1846 creation of the American Medical
Association, and b) the Nuremberg Code for research ethics, established in the aftermath of World War II, on the use of human subjects in experimental research (Mitscherlich & Mielke, 1947). In 1979, the U.S. Department of Health and Human Services issued the first historical document on ethical principles and guidelines for the protection of human subjects. This was known as “The Belmont Report” and provided a set of bioethics-inspired principles of respect, beneficence, and justice as the foundation for use of human subjects in medical research (DHHS, 1979).

Most recently, the 2009 Presidential Commission for the Study of Bioethical Issues for the first time addressed more broadly the bioethical issues related to advances in biomedical sciences research and biotechnology and explored SPD options to ensure the freedom to pursue scientific research and innovative technology development in a socially and ethically responsible manner (DHHS, 2012). These guidelines offer a conceptually cohesive framework to the more challenging task of crafting SPD approaches taking into account the difficult bioethical issues surrounding the spectacular progress in biomedical and genomic research. It is relevant to note that the conceptual elements of SPD and regulatory mandates and treaty obligations have interdependencies, and the overall effectiveness of the former is linked to the policy-guiding development and implementation of the latter.

Figure 2 illustrates the interdependency of SPD with the policy-making and regulatory establishment and implementation process. Mandatory regulations by design require compulsory compliance and stipulate penalties for noncompliance. Hence, success in a large measure depends on faithful compliance by the regulated community, which is where SPD tools and methods come into play. Defined more broadly as a process that effects a change in attitude upon a willing subject without invoking the regulatory mandates, SPD aims to enhance voluntary stakeholder participation towards the broader regulatory objectives set forth under the mandates. Simultaneously, SPD tools and methodologies offer the regulatory community feedback on the mandates to allow further modifications in the regulatory process to improve implementation effectiveness and to better coordinate with the regulated community. Therefore, maintaining internal consistency with mandatory regulation is a crucial aspect in the formulation of SPD strategies. We propose bioethically-inspired SPD tools and methodologies be closely linked to the existing regulatory process to ensure consistency in communication and to assess overall compliance.

Key criteria would involve identification and delineation of the essential conceptual elements of SPD architecture. The decision-making process in a clinical or laboratory setting among two or more seemingly conflicting choices often revolves around anticipated positive or negative outcomes at different levels:

**Figure 2**

Bioethical principles guide formulation and interpretation of soft power diplomacy initiatives and its interdependency with hard regulatory mechanisms.
a) The first set of decision points revolves around individual needs and interests weighted against those of the community, where choices may present options beneficial to one while placing a serious burden on the other.

b) The second set of decision points revolves around short- and long-term benefits, where options offering immediate short-term benefits require careful consideration of long-term impact on human society and the general environment.

c) The third and final set of decision points revolves around the balanced consideration of administering justice as opposed to the relevance of mercy to the affected community. For example, the decision to provide licensure for a new category of medical countermeasures may address a serious public health problem but at the same time pose an unquantified measure of risk to population subgroups likely to be exposed to the new medical countermeasures.

Bioethics-inspired SPD should recognize the basic dilemma presented in each of these decision points where competing values are at play. Therefore, the need for a SPD-guided decision-making process would extend beyond the professional communities and their governing institutions. The bioethics-inspired SPD roadmap would have to engage a broader participation of society-at-large since the overall impact is on the human society as a whole. A global bioethical network of broader stakeholder communities will be actively involved in the formulation of SPD tools and methodologies that go beyond the narrow confines of regulatory mandates.

Figure 3 illustrates the functional components of bioethics-inspired SPD tools and methodologies, where considerable emphasis is placed at the individual and institutional level and provides transparency to a wide array of stakeholder communities throughout the network.

Nodal elements participating in the network would participate in dialogue and discussions ranging from: a) initiatives to modify behavior at the individual level that results in self-governance; b) balanced consideration on threats to populations versus individuals as in the case of bioterrorism; c) methods to safeguard DURC and intellectual properties produced through research; and d) approaches to improve biosecurity without hindering the advancement of biomedical science research and technology innovations.

As illustrated in Figure 3, the proposed SRM tools and methodologies of a global bioethical network are directed primarily at individual scientists and the institutional-level decision makers with a guiding rationale that better outcomes are realizable when implemented proactively as a voluntary initiative to broadly promote education, awareness and active participation:

- **Peer-review** (for both ethics and safety) of research proposals to ensure that proposed research is fully vetted prior to initiation of the project. Articles are already being reviewed by most of the popular publications to ensure that gained knowledge is not publicly available if it should be determined a threat to biosecurity (Johnson, 2012).

**Figure 3**

Soft power diplomacy tools and methodologies constituting the conceptual architecture for a Global Bioethical Network guide national security policymakers and the stakeholders in the scientific community.
• **Research checklists** to aid scientists in determining if their research takes into account all the concerns of biosecurity and also to help ingrain the standards through repetitive use of the tool.

• **Dual-use plan** for publicly funded projects in the future (e.g., animal use plan). Currently, biosafety plans are required when submitting grant proposals, but it should become a standard practice for government-funded research to also require a plan to ensure the protection of dual-use information through a “dual-use plan.”

• **Clearinghouse** for scientists to direct questions and to determine if a piece of information or specific research area is a biosecurity concern.

• **Advisory boards** at the state level similar to the U.S. National Science Advisory Board for Biosecurity (DHHS, 2012) with the aim to better utilize local and regional capabilities for oversight and to promote educational awareness.

• **Research assessment template** for individual assessment of potential research.

• **Global forums and NGOs** can serve as venues for best practices and experiences to be shared. We should focus on creating communities at this level and down to the individual.

• A list of proposed obligations for life scientists as a set of standard, widely accepted, best practices from peers across the field.

• **Training** on best practices.

As illustrated in Figure 3, performance outcome depends on proactive initiatives at the individual level and voluntary participation of institutions in the overall process. Unlike the established regulatory framework that depends solely on enforcement by authorities at the national and international levels, the SPD framework for the bioethical network is proactive, participatory, and fundamentally based on the awareness of the community.

National science policymakers have considered policy options and research standards, and best business practices to oversee DURC without compromise on the essential core tenants of the freedom to pursue biological research (Shea, 2007). These efforts are in concert with concurrent initiatives from the scientific community (NRC, 2004). However, the framework outlined in this study formally integrates a systems approach to the evolving consensus in the scientific community towards simultaneous measures that promote self-regulation at the individual level and better biosecurity measures at the institutional level, both supported by increased biodefense-related awareness and educational programs (Dolgister, 2007).

The global bioethical network would serve as the SPD architecture to develop in a proactive manner in tandem with major international forums, such as the Interessional Working Groups of the BWC and the World Health Organization, aimed at broadening the network of communities and providing a forum to develop and test novel SPD tools. These tools are aimed at improved awareness of biological risks and a better understanding of the threats posed by new and emerging infectious diseases. The network would provide a forum for sustained interactions among various participants and a cross-cultural dialogue on the development of national systems for research ethics, education, and outreach.

**Recommendations**

National security policymakers examining alternate options to meet the goals of biological threat reduction through treaties and hard regulations ought to place more emphasis on the potential role of SPD tools and methodologies for developing universal norms towards open-source bioethics. Policymakers should note the effective precedence in the contemporary international arena to articulating SPD approaches as alternative options to meet the goals and objectives of the treaty- and legislation-based hard regulations.

• **Leverage growing awareness**: National security policymakers should consider SPD-based policy alternatives to more effectively leverage the growing awareness among scientific researchers towards self-regulation and the promotion of responsible conduct in research. Institution-level guidelines on research misconduct, safe handling of sensitive data and materials, and a peer-review process in research publications that takes biosecurity into account are also required. Clearly, regulatory mandates and international treaties are partial solutions to addressing the sensitive and contentious bioethical challenges associated with biological threat reduction and biosecurity.

• **Alternative options to empower regulatory mandates**: A bioethics-inspired SPD framework has the power to dramatically alter the nature of discussions related to biosecurity in the life sciences research enterprise. In particular, the dynamic of the SPD framework should address the shortcomings in existing regulatory mandates in the biotechnology-driven Bioeconomy, where not much is known of its inherent hazards and potential long-term impact on human society, the general environment, and national/international security.

• **Engage the global community on the merits of SPD initiatives**: Bioethics-inspired SPD is attractive for its enduring quality of high-order thinking that shapes quality-of-life goals. A deliberate process aimed at embracing the moral dimensions of human endeavors, such as in conducting research with troubling ethical dimensions, with the potential to adversely impact health and the general environment, will guide decision making at the operational level.

• **Integrate bioethics-based SPD as part of education curricula**: Given the broad interdisciplinary nature of the SPD tools and methodologies, universities and institutions should develop educational and specialized training programs catering to students pursuing careers in science and technology, law, public policy, and business. These training programs should focus on the nonbinding rules or instruments in the SPD and approaches to integrate these tools within the existing regulatory framework. Biosafety professionals have stressed the value of well structured educa-

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tional programs on codes of conduct, biosafety, and biosecurity as a prerequisite for graduation in advanced university education and training programs (Johnson, 2006).

Bioethics-inspired SPD tools and methodologies could also play a meaningful role in biological arms control and biological threat reduction goals. They could aid in carefully evaluating and deciding among a series of competing options, but with the inherent recognition that there is no single moral course of action. Active participation from the scientific and policy communities is essential to further articulate the influential role of SPD in countering bioterror proliferation and to gain participation of other stakeholders towards implementation using other successful models outlined in this article.

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Training Announcements

Principles & Practices of Biosafety (PPB)
This is a comprehensive, interactive, 5-day course that introduces the essential elements of biosafety and provides
extensive resource lists for use after the course. Interactive exercises are used throughout to provide hands-on experience
and to encourage networking and problem solving among participants and instructors. Upon completion of the course,
participants will be able to: describe potentially hazardous biological materials, the risks associated with their use, and the
means to minimize risk and to protect against or prevent release or exposure; discuss ways to provide effective technical
expertise in situations involving potentially hazardous biological materials; and, identify, locate, and efficiently use key
biosafety resources. This course is designed for persons who are entering the profession and those with up to three years
experience in biosafety. It is also suitable for persons who supervise biosafety professionals and for those who will benefit
from additional knowledge of biosafety as a complement to their primary responsibilities. To register for the PPB at the
Embassy Suites Orlando—Lake Buena Vista South in Kissimmee, Florida from February 24 to March 1, 2013, go to

6th Annual Leadership Institute
The 6th Annual Leadership Institute will be held from April 15-18, 2013 at the Charleston Marriott in Charleston,
South Carolina. For more information, go to www.absa.org/eduleadership.html.