Legal and Moral Reflections on Modern Biotechnology in Use & Misuse*

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Only the law can tame the unleashed genie of science, so that it remains the servant, not the master of mankind....Without adequate legal control, our affluent society could become an effluent society!

Honorable Chief Judge Howard T. Markey

1. Introduction

It is an established truth that science serves humanity by developing new and useful technologies, discovering new phenomena, forwarding knowledge and understanding. ‘Science seeks certainty … and tells us what we can do… but it is for the law to tell [science] whether and how to do’, even if it is in a climate of uncertainties. As a natural phenomenon, scientists tend to concentrate on the beneficial uses of scientific research, but each of them should also concentrate on the potential destructive misuses, in as far as is known, assumed or reasonably predicted. Considering the fast accumulation of sophisticated scientific and biotechnological information, it is upon the scientist and his community to inform and warn the public about the potential destructive misuses of biotechnological research and findings. It is instrumental for the public to be aware of the risks posed by certain dangerous biological agents that are used, manipulated or developed in the course of biotechnological research. The public must be aware of and be reminded that certain biological agents can be used as biological lethal weapons for mass-destruction, or misused for deliberately inflicting infectious diseases. This can be done either by directly spreading common pathogens or by indirectly contaminating food-products, water resources, crops, animal food and feed, etc. It is known that certain lethal biological agents can be transformed into more lethal forms or may even be specifically engineered as such. It is upon the public at large, in applying its collective moral conscience, guided by relevant knowledge and information, to choose what scientific research and advanced technologies should be furthered, banned, or temporarily withheld.

It is to be emphasized that the international community has already long ago expressed its determination ‘to exclude completely the possibility of bacteriological...
(biological) agents and toxins being used as weapons…[it being] repugnant to the conscience of mankind”.

In signing the Biological and Toxin Weapons Convention of 1972 (BWC), in adherence with the Geneva Protocol and principles of the UN Charter, each State Party undertook:

[N]ever, in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; [and or] (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

However, the BWC does not contain a mechanism for its implementation. It was observed that because of the dual-use possibilities and blurred borders between peaceful and offensive uses of biotechnology, it is difficult to implement the BWC. In being an international instrument, its implementation was and still is in the realm of each nation. This is an ongoing task. It is instrumental to implement the strict prohibitions vital for the survival of humanity, but it is also instrumental to ensure the furtherance of peaceful biotechnological research.

Freedom of scientific research, publication and dissemination of its findings is recognized in the civilized world as part of the human basic right for ‘freedom of expression’. It is in the public interest to observe and protect these rights. However, in confronting today’s threats and potential dangers, it is imperative to frame their protection within a legal framework, adequately balancing between ‘fair and legitimate uses’ and the potential ‘destructive misuses’. Modern biotechnology has to strike the delicate balance between conflicting and competing interests, in order to protect the scientist in his working environment, and the public at large, in its extended environment. This has to be the ‘oracle’ and guiding code of all scientific research and its neighboring activities. Commercialization of biotechnological findings became an important vehicle in the knowledge-based global economy, but it is the law that makes them merchantable by securing their intellectual property rights. It is upon the law, and especially intellectual property law, to act as the ‘Gatekeeper’ of ‘Morality and Public Order’, and ‘to tame the genie of science’, although not too severely, for the present and future generations. There is a need for an interactive collaboration between the scientific community, the public at large, through its legislative bodies, the legal practitioners, the media and the judiciary in providing a balanced adequate normative infrastructure, designed for ensuring furtherance of

3 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and their Destruction (BWC), signed on April 10, 1972.
4 Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on June 17, 1925.
5 Article 1 1972 BWC, supra note 3
6 See Jayantha Dhanapala, U.N. Under-Secretary-General for Disarmament Affairs, Opening Statement for the in BioWeapons Prevention Project Launch, Geneva, Nov. 11, 2002, available at <http://disarmament.un.org/speech/11nov2002.htm> (as of May 2008).
scientific research and free dissemination of its results, subject to protection of public health, security and safety.

1.1 Biotechnology in the Dual-Use Dilemma

Although biotechnology is not a new technology, in the last 30-40 years it demonstrates itself in a diversity of new ‘get-ups’ and a wide range of new procedures, such as genetic engineering; bioengineering; artificial selection, modification and manipulation of biological agents. All the laboratory-based techniques such as rDNA; tissue culture processes, gene-transfer techniques and other various methods for manipulating organic material, are applied with a purpose to serve humanity, medicine, agriculture, animal life, food-supply and the environment. Dispersion of knowledge, rapidity of innovation and invention are encouraged by the social and economic regimes of many nations. This is also the case for biotechnological research and its flourishing development for procurement of new products and processes.

The major components of biotechnology are ‘biological agents’ which are dealt with, kept, developed, used for research, handled, possessed, stockpiled or transferred, almost daily, in the realm of institutional or private biomedical and microbiological laboratories, or on the premises of biotechnological industries. Many new techniques and procedures are invented for manipulating and treating biological agents and a wide range of innovative equipment is available. Until not long ago the main concern, surrounding practice and research in biology, was focused on safety measures in the ‘work place’, mainly for the protection of researchers and ‘workers’, dealing in dangerous biological agents, especially in microbiological laboratories. Microbiological laboratories have been considered as work places that pose infectious disease risks to persons that work in the laboratory or are in its vicinity. The history of microbiology describes laboratory-associated infections and cases of typhoid, cholera, brucellosis, and tetanus. A number of cases were attributed to carelessness or poor technique in the handling of infectious materials. ‘Handling of cultures or specimens or the inhalation of dust containing dangerous organisms [was found] eminently dangerous to laboratory workers…’; 7 ‘Exposure to infectious aerosols was considered as the most common source of infection.’8 In the 1990s, a growing concern was expressed about the re-emergence of M tuberculosis. The ‘routine application of recombinant DNA technologies has required a thorough risk assessment of their inherent unknowns.’9

7 See STEBBINS, Biological Weapons Production, available on the website for the Federation of American Scientists (FAS) at <http://www.fas.org/programs/ssp/bio/resource/introtobw.html> (as of May 2008).
8 See Introduction, in RICHMOND/MCKINNEY (eds), Bio-safety in Microbiological and Biomedical Laboratories (4th ed. 1999), available at <http://www.cdc.gov/OD/ohs/biosfty/bmbl4/bmbl4toc.htm> (as of May 2008).
9 Id. See also STEBBINS, ‘Some lessons learned from the Anthrax Attacks’, SEEDMAGAZIN.COM, Materials & Processes, October 2, 2006, available at <http://seedmagazine.com/news/2006/10/some_lessons_learned_from_the.php> (as of May 2008).
Nevertheless, it seemed that the scientific community assumed that in the course of scientific research, all manipulations with biological agents are legitimate for beneficial R&D. For years, a strong tendency has existed by the scientific community, to oppose intrusive regulation of their work. It was widely propagated and accepted that all scientific research has to rely on self-governance by the scientists depending on their integrity, morals and stringent ethical rules, rather than being incarcerated into legal normative frameworks, prescribed by the legislators.

Unfortunately, in result of the tragic events of September 11, 2001, followed by a wave of Anthrax envelopes dispatched in the USA, the attention of the world community has been focused on the hazardous aspects of biotechnology, which although known from before, were somehow, generally disregarded. The recent events have tilted the balance, justifying rethinking of existing policies and change of approach. It became clear that biotechnology in its manifold ‘get-ups’ and ‘dual-use’ processes and products, alongside its legitimate uses, poses a ‘clear and present danger’ if used for destructive purposes. The world community has been reminded that certain biological agents, e.g., toxins, viruses and bacteria, innocently dealt with or invented and developed for scientific research or medicine have been and can be used as biological weapons for mass-destruction. This depends on the nature of the biological agent, its preparation; its ability for ‘survival’ in the environment; its dispersion ability; scope of contamination, etc. Scientific writings underlined the difficulty in detectability and the delayed "ouevert effect" of a released biological agent. Voices stressed the simplicity of access to dangerous biological agents, easy development and simple employment for bioterrorism in whatever destructive manner, ‘not entailing excessive costs’!

Pathogens can be obtained from...[their] natural environment, ... [from] a microbiology laboratory or bank ... An alternative to acquiring agents is creating them ... Advances in biotechnology have made it possible to synthesize certain viruses based on their genome, or on genetic instructions ... or to modify agents and alter their function.\(^\text{10}\)

It was stressed that agents modified for increased pathogenecity and a shorter incubation period could cause severe, fast-acting diseases. Other modifications could make treatments, vaccines, or the body’s immune system, useless.\(^\text{11}\) Attention was drawn to possible dangers if deadly microorganisms may unintentionally, through negligence or carelessness, ‘escape’ from a laboratory or while in transit. It was also stressed that in course of dealing with such agents, a scientist may not knowingly become infected by a life-threatening disease and become a carrier of it into his community or even further. In cases of recklessness or negligence, he may enable access to such agents for hostile purposes.

\(^{10}\) See supra note 8

\(^{11}\) See STEBBINS, ‘Biological Weapons Production’, available on the website of the Federation of American Scientists (FAS) at <http://www.fas.org/programs/ssp/bio/resource/introtobw.html> (as of May 2008).
It is claimed that biotechnology has reached its peak and enables unlimited intervention in any life form on earth, providing tools to shape future generations and even substitute life forms by synthetic living organisms built ‘from scratch’. It has been observed that many of the new techniques, tools and technological equipment used in beneficial procedures are misused for destructive manipulations using the same knowledge, sometimes obtained from easy accessible scientific literature. Questions are raised as to its openness.

Considering the duality of biotechnological R&D, it is essential that each practicing scientist, in working with dangerous agents liable to be used as biological weapons, should remember at each stage of his scientific work that he is in the forefront for preventing or minimizing any possible misuse. He is the master of knowledge, thus it is his responsibility to take precautionary measures, in as much as possible and reasonable, in order to prevent such occurrences. Adherence to ethical guidelines and moral principles by each individual scientist and his peers is very important, but apparently not sufficient, anymore.

It is important not to withhold incentives for innovation, encouraging development of countermeasures and promoting investments secured by the patent systems. However, it is more important to ensure that the inventors and investors be aware of the dangers their enterprises may pose to public security, health and safety. The general clause denying patentability to inventions challenging ‘public order or morality’ may prove its impotency in such cases.

Biological weapons such as disease-causing bacterial agents have a long history of being used in battle along chemical and nuclear weapons, for military purposes and not just as strategic deterrents. It is reported that ‘natural pathogenic microorganisms, such as anthrax, plague, yellow fever, smallpox and their toxic products were used in weaponization processes by culturing these agents, converting and using them in powder or liquid form, for arming rockets, warheads short or long range missiles, etc’. It is recognized that the dual-use characteristics of biotechnology and its products pose a difficult dilemma for the scientific and legal communities and for the public at large. However, while science races ahead in an unprecedented pace, law limps heavily in its far back and the public remains dormant until some disaster scares it. Considering the new developments and the presently known dual-uses of biotechnology, it may be said that there is already a public consensus that biotechnological research in dealing with dangerous biological agents requires a strict and comprehensive normative framework. Although the Geneva Protocol prohibits use of chemical and biological weapons in warfare and the BWC restricts countries from developing, producing, stockpiling, or acquiring biological agents, weapons, and equipment outside of peaceful purposes, these international legal instruments are not equally implemented. Many of the signatory nations, in adhering to the convention, have prohibited further development of biological weapons

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12 See e.g. HOLT, Synthetic genomes brought closer to life, 26 Nature Biotechnology 296 (2008) reporting on Craig Venter’s invention of synthetic DNA. Craig Venter’s first successful synthesis of a genome was published earlier that month, see GIBSON ET AL., Complete Chemical Synthesis, Assemble and Cloning of a Mycoplasma Genitalium Genome, 319 Science 1215 (2008).
and destroyed their existing arsenals, but it is known, that some of the adhering parties have secretly continued and some non-parties are even hurriedly competing in developing new sophisticated biological weapons.

It should be mentioned that most nations in the civilized world have provided bio-safety regulations aiming to ensure safe practice and control in ‘dealing’ with dangerous biological agents in microbiological and biomedical laboratories. These statutory provisions are reviewed by their legislators from time to time. It is widely recognized that ‘strict adherence’ to these [regulations] is contributing ‘to a healthier and safer work environment for researchers, their co-workers, and the surrounding community’. However, this does not override the general resistance of the practicing scientist towards ‘intrusive’ regulation of biotechnological research and its products. Some scientists still proclaim their preference for ‘wild science’ to be self-governed, rather than regulated by legislators. Regulating the publishing of scientific material is strongly criticized. Recommendations for self-screening by scientists and editors of scientific journals, is strongly propagated. It is claimed that considering the affluent sources of biological information, regulating scientific publications on a national level, is useless.

But as said, in light of the disastrous events and future threats and dangers in the year of 2001, long existing concepts begin to change. It became clear that a thorough examination of the existing bio-safety regulations in the field of biotechnological research is to be performed with a view on bio-security, subject to national security concerns of each nation. Increased awareness, preparedness and an immediate vigorous response to the serious threats on public health, safety and security, became an immediate must. Policymakers, the legal and the scientific community at large, were urged to give an adequate response to this challenge.

Some nations responded immediately in a comprehensive well-balanced manner, some in a hasty non-balanced manner, and some have not responded, yet.

1.1.1 A Random-Look on Bio-Safety & Bio-Security Provisions

Shocked by the disastrous attack of September 11, 2001, on the World Trade Center, followed a week later, by letters containing anthrax spores, which killed five people, infected 22 others and caused an international trauma, many nations, e.g., the United States, the United Kingdom and the European Union, responded to the emergency situation, quickly and vigorously. Existing legal frameworks regulating biotechnological research were strengthened, criminal punishment toughened and new stringent legislation was enacted to prevent use of biological agents as weapons of mass destruction, prohibiting malicious transfer or intentional destructive release. Stricter oversight and inspection procedures and enhanced safety and bio-security measures were prescribed for applying in biomedical laboratories, dealing with ‘dual-use’ dangerous biological agents, in order to prevent unwanted access to or unintentional escape or seepage of these agents.

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13 Supra, note 8, chapter on ‘Bio-safety measures’.
14 See Michael T. Osterholm, ‘A Weapon the World Needs’, 435 Nature 417, 418 (May 2005)
15 See Hatfill v. New York Times Co., 488 F. Supp 2d 522 ; 2007 U.S. Lexis 7295 (E.D. Va. 2007).
Congress responded promptly by enacting the USA Patriot Act of 2001, with the aim, (as is also apparent from its full official title) ‘to deter and punish terrorist acts in the United States and around the world….’ The Act strengthened the criminal law in combat against terrorism, enhanced law enforcement in regards to the use of weapons of mass-destruction and introduced drastic investigatory tools and interrogative mechanisms. Severe penalties were prescribed for knowingly possessing (in certain circumstances), ‘biological agents, toxins, or delivery systems’, especially by certain restricted persons; enhanced domestic security was provided and assistance in enforcement of Criminal provisions was extended.

In trying to define the ‘non-definable’, the Patriot Act provided (in amending the Fed. Criminal Code), in a very wide-embracing non-definitive manner that:

‘international terrorism’ includes activities ‘that appear to be intended to affect the conduct of government by mass destruction’ and ‘domestic terrorism’ includes criminal acts ‘dangerous to human life, that appear to be intended to intimidate or coerce a civilian population, to influence government policy…., or to affect government conduct by mass destruction, assassination, or kidnapping’.

The Act provides jurisdiction over crimes committed at U.S. facilities abroad; neutralizes the statute of limitations for certain terrorism offenses; prescribes penalties for attempts and conspiracies, ‘the same as those for terrorism offenses’. It contains stringent measures for confiscation and seizure of property, enhanced surveillance procedures, money laundering counter measures, disclosure of suspicious bank-activities, etc.

The USA Patriot Act 2001, in being enacted as a vigorous tool to combat world terrorism has extended and enhanced an already existing substantial body of provisions relating specifically to biological weapons, namely The Biological Weapons Anti-Terrorism Act of 1989 and The Antiterrorism and Effective Death Penalty Act 1996.

The Biological Weapons Anti-terrorism Act 1989 by implementing the 1972 Biological Weapons Convention and in compliance with it, provided, by amending the Criminal offences that:

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16 See ‘The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, USA Patriot Act ( Public Law No. 107-56) enacted on October 24, 2001
17 See Sections 103-105.
18 See Sections 804; 809-811 of the Patriot Act.
19 See Sections 106; 203; 209 of the Patriot Act.
20 See The Biological Weapons Anti-Terrorism Act of 1989, Public law 101-298, signed May 22,1989.
21 See The Antiterrorism and Effective Death Penalty Act 1996 (AEDPA), Pub.Law 104-132 signed April 24, 1996 (following the blast on the Federal building in Oklahoma City).
Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, – shall be fined … or imprisoned for life or any term of years, or both.22

With the aim not to restrict scientific research, the BWAT specifically proclaimed that: ‘Nothing in this Act is intended to restrain or restrict peaceful scientific research or development.’23 The Act clearly stated that the prohibition on using biological agents does not apply to uses ‘for prophylactic, protective, or other peaceful purposes’. Violation of a prescribed prohibition is punishable by imprisonment from ten years to life imprisonment.24

In broadly defining the meaning of a ‘biological agent’, ‘Toxin’, ‘Delivery system’, and ‘Vector’,25 the Act provided that any biological agent or toxin ‘of a type or in a quantity that under the circumstances has no apparent justification for prophylactic, protective, or other peaceful purposes’, may be seized and destroyed.

The Antiterrorism and Effective Death Penalty Act 1996 prescribed strict control of biological agents and authorized the Secretary of Health and Human Services (HHS) to regulate the possession and transfer of potentially hazardous biological agents, in order to prevent exposure to such agents and protect public health and safety. It strengthened penalties for threatening, attempting, or conspiring to use a biological agent as a weapon for mass-destruction. It extended the definition of ‘biological weapons’ by including engineered biological products, infectious substances and bioengineered components of a microorganism, virus or biological product. Also ‘toxic material of plants, animals, viruses, fungi or infectious substances or a recombinant molecule that may be engineered as a result of biotechnology’ were included under ‘Biological Weapons Restrictions’.26

Aware of the potential hazards from biological agents, in stressing the importance of the precautionary principle, the AEDPA 1996 imposes on the Secretary the duty to establish and maintain, through regulations, ‘a list of each biological agent that has the potential to pose a severe threat to public health and safety’. In determining whether to include an agent on the list, the Secretary shall consider:

[T]he effect on human health from exposure to the agent; the degree of contagiousness of the agent and the methods by which the agent is transferred to humans; the availability and effectiveness of immunization to prevent and treatments for any illness resulting from infection by the agent; and any other criteria that the Secretary considers appropriate.

In deciding on all these the Secretary shall consult with scientific experts representing appropriate professional groups.27 The Secretary shall, by regulations, prescribe

22 See Title 18 US inserted chapter 10, sections 175-178.
23 See Sec. 2 of the BWAT ‘Purpose and intent’ and Sec.175 (a)&(b) Title 18 , chapter 10
24 Extraterritorial Fed. Jurisdiction is afforded to such offenses, if committed by or against a national of the US.
25 See Definitions, BWAT 1989
26 See Section 511 (a-e) of the AEDPA 1996.
27 See Section 511 (d)(1)(A)&(B) of the AEDPA 1996.
safety requirements and procedures for the transfer of biological listed agents and for the ‘proper training and appropriate skills to handle such agents’ and also for ‘proper laboratory facilities to contain and dispose of such agents’. The Secretary shall ensure safeguards to prevent access to such agents for use in domestic and international terrorism or for any other criminal purpose and shall establish procedures ‘to protect the public safety in the event of a transfer or potential transfer of a biological agent in violation of the safety procedures….’28 In securing furtherance of scientific research and development, the act stipulates that measures shall be provided to ensure ‘[a]ppropriate availability of biological agents for research, education and other legitimate purposes’.29

Subsequently, with the aim to further ‘[i]mprove the Ability of the US to Prevent, Prepare for and Respond to Bioterrorism and other Health Emergencies’ the U.S. congress enacted The Public Health Security and Bioterrorism Preparedness & Response Act of 2002.30 In its operative wide-embracing manner the Act requires development and implementation of a coordinated strategy to be periodically reviewed and revised, if needed. It shall include provisions for ensuring appropriate capacity to detect and respond effectively to bioterrorism and health emergencies (laboratory readiness; properly trained and equipped emergency personnel; health and safety measures for such personnel, etc.). Timely dissemination of relevant information to the public, via communications networks, is to be ensured as a safety measure. Invention, development and maintaining of medical countermeasures, is to be strongly encouraged.31 ‘Security should be provided for R&D of countermeasures, and for evaluation and production of new and emerging technologies against Bioterrorist attacks and other public health emergencies….’32 ‘Stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies… appropriate and practicable [for health security]… in the event of a bioterrorist attack’ should be maintained.33

In its wide spectrum of prescribed ‘Enhanced Regulatory Control of Certain Biological Agents and Toxins’, the Act stresses the necessity and importance of maintaining, by regulations, the ‘list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety’.34 It also repeats the same criteria as prescribed by the AEDPA 1996, with slight changes in the consultation process. The Act provides that the list is to be reviewed and republished biennially, or more often and revised as needed.35 Standards and procedures for governing the possession and use of listed agents and toxins shall be established by

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28 See Section 511 (e)(1)(A)&(B), (2)&(3) of the AEDPA 1996.
29 See Section 511 (e)(4).
30 See Public Law 107-188 107th Congress, June 12, 2002.
31 See Subtitle A Section 101 & 2801 subsec. (a), 2(b)(A)(B)(C)(F)& (3).
32 See Subtitle B, Section 121(a)(1) (2)(D) & Sections 124 -126.
33 See Subtitle B, Section 121 (a)(1) Public Health Security &Bioterrorism Preparedness & Response Act 2002.
34 See Sec 351A (a)(1)A of Public Health Service Act, Title III (42 USC 262 et seq.).
35 Amending the Public Health Service Act (42 U.S.C. 262 et seq.), by inserting Sec. 351A (a)(2).
Regulations. Registration procedures shall ensure that persons seeking registration ‘have a lawful purpose to possess, use, or transfer such agents and toxins’. Information in regards to details and characterization of listed agents and toxins shall be required to facilitate their identification, including their source. A national database shall be maintained by the Secretary and is to include the names and locations of registered persons; the listed agents and toxins that such persons possess, use or transfer and information regarding their characterization. A prompt notification is to be given to the relevant enforcement agencies in case of theft or loss of listed agents. A registered person shall give prompt notification whenever a release of a listed agent or toxin has occurred outside of the bio-containment area of his facility. If such release poses a threat to public health or safety, the Secretary shall immediately notify the relevant authorities (local, State or Federal) and the public. Compliance with these requirements shall be ensured by the Secretary, in consultation with the Attorney General, as part of the registration system. Requirements and limitations for access to listed agents should be imposed by regulations in accordance with stringent stipulations by law. Upon receiving the names and other identifying information the Attorney General shall, identify ‘whether the individuals involved are within any of the [suspected by the act] categories’, and shall ‘promptly use criminal immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose’. Exemptions are prescribed for clinical or diagnostic laboratories by providing that:

Regulations under subsec (a) and (b) shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that (A) the identification of such agents or toxins is reported…; and (B) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation. Products shall also be exempted if the ‘products are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the Acts.’ The Secretary shall have the authority to inspect persons subject to the regulations…to ensure compliance with these regulations.

36 See Section 351A (id)(c ) of Public Health Service Act.
37 See Section 351A (d)(1)(2) & (e) of Public Health Service Act.
38 See Section 351A (d)(1)(2).
39 See Section 351A (e)(9).
40 See Section 351A(e)(1).
41 See Section 351A(e)(2).
42 See also 18 U.S.C. Section 2331 and 50 U.S.C. Section 1801.
43 See Sec. 351A (g)(1)(a)(b).
44 See Sec. 351 A(g) & sec. 351(1)(2) A of the Act under ‘Exemptions’.
45 See sec. 351 A (f)
An additional Act, the *Project Bioshield Act (2003)*, was enacted with the aim to protect public health from biological terror. The Act provides authority for use of certain procedures regarding biomedical countermeasure research and development activities in stating that the Secretary may conduct and support such activities if these concern ‘*qualified countermeasures*’ (a priority countermeasure that affects national security). The Secretary may require, in any grant or agreement ‘with respect to a bio-containment laboratory or other related or ancillary specialized research facility…necessary for …performing, administering or supporting qualified countermeasure R&D’, that the facility of the recipient of such a grant ‘shall be available as needed to the Secretary, to respond to public health emergencies affecting national security needs.’\footnote{See, Sec. 319F -1(a-h) of the Project BioShield Act of 2003}

It is to mention that on January 31, 2007, the U.S. President issued a Directive\footnote{See, Sec. 319F -1(a-h) of the Project BioShield Act of 2003} drawing upon the ‘potential of the scientific community in the public and private sectors to address [the] medical countermeasure requirements relating to CBRN [chemical, biological radioactive and nuclear] threats’. These have to ‘balance the immediate need to provide a capability to mitigate the most catastrophic, current CBRN threats, with long-term requirements to develop more flexible broader spectrum countermeasures, to address future threats’.

1.1.1.2 United Kingdom

A special *Anti-terrorism, Crime and Security Act 2001 (ATCSA)*\footnote{See, Ch. 24 Sec.43 & Sec 50. Eng. BW A 1974.} was enacted amending the existing *Biological Weapons Act 1974 (BWA 1974)*\footnote{See Biological Weapons Act 1974, (BWA 1974) Ch. 6. Sec.1 Eng.} which prescribed ‘restrictions on development of certain ‘biological agents, ‘toxins’ and ‘biological weapons’ in providing that:

No person shall develop, produce, stockpile, acquire or retain –

(a) any biological agent or toxin of a type and in a quantity that has no justification for prophylactic, protective or other peaceful purposes; or

(b) any weapon, equipment or means of delivery designed to use biological agents or toxins for hostile purposes or in armed conflict.\footnote{See Section 1(1) of the Biological Weapons Act 1974.}

In consequence of the amendment, a new inserted Section 1(1A) extends the spectrum of deterrence by prohibiting transfer or entering into an agreement for transfer, or making arrangements for transfer of any biological agent or toxin, (by any person to another person or by others), ‘if the biological agent or toxin is likely to be kept or used otherwise than for prophylactic, protective or other peaceful purposes and he knows or has reason to believe that that is the case’.\footnote{See Section 1 (1A)(1).}

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\footnote{See Homeland Security Presidential Directive/HSPD-18, available at <http://www.whitehouse.gov/news/releases/2007/02/20070207-2.html> (as of May 2008).}
viction upon indictment, be liable to imprisonment for life. ‘Biological agent’ and ‘Toxin’, are defined as ‘any microbial or other biological agent or toxin – whatever its origin or method of production’. The range of prohibited punishable acts was extended by including ‘attempt, preparation, conspiracy, assistance, promotion, persuasion, and other acts and extraterritorial jurisdiction applies ‘to acts done outside the UK, but only if they are done by a UK person’. The Anti-Terrorism, Crime and Security Act (ATCSA) in dealing with ‘weapons of mass-destruction’ prohibits any conduct of ‘aiding, abetting counseling procuring or inciting a person who is not a UK person ‘to do a relevant act’ outside the UK is an offence punishable by life imprisonment. It is not necessary to have any particular person in mind as the person in whom he intends to induce the belief in question’.

The Health and Safety at Work etc. Act 1974 aims to protect health, safety and welfare in connection with work, and ‘Control of Dangerous Substances and Certain Emissions into the Atmosphere’. It prescribes general duties for employers and self-employed persons, of such undertakings, towards persons other than their employees, thus extending protection to the wider public.

It shall be the duty of every employer to conduct his undertaking in such way as to ensure, so far as is reasonably practicable… that he and other persons (not his employees) who may be affected [by his conduct with dangerous substances…] are not thereby exposed to risks to their health or safety….

In such cases it shall be his duty to give, to persons who may be affected, ‘the prescribed information about such aspects of the way in which he conducts his undertaking as might affect their health or safety.’

1.1.1.3 European Union

A communication from the EC to the Council and EP, was issued on November 29, 2001, in regards to ‘Civil Protection’, stating that in consequence of the unprecedented outraging terrorist attacks of September 11, 2001 in the USA, the European community and its individual members are ‘prompted to enhance their preparedness and readiness to prevent or mitigate the impact of such reoccurring terrorist attacks’. All the relevant bodies were asked to prepare a program designed for

52 See Section 1 (1A)(3) of the BWA 1974.
53 See Section 1 (1A(2)of BWA 1974.
54 See Section 1A of BWA 1974.
55 See Anti-terrorism, Crime and Security Act 2001 (Ch. 24., Section 50 Subsec. 4 + Subsec. 7 Eng.).
56 See Anti-terrorism, Crime and Security Act 2001, Ch. 24, Section 115 (Eng.) Sections 113+114 supplementary).
57 The Health and Safety at Work etc. Act 1974, Ch. 37,Section 3 Eng.
58 See Section 3(1) of The Health and Safety at Work… Act 1974 (Ch. 37) Eng.
59 See Section 3(1)(2) & 3(3) of the Health and Safety at Work…Act 1974.
60 See Communication from the Commission to the Council and the European Parliament – Civil Protection – State of Preventive Alert against Possible Emergencies of November 29, 2001, COM (2001) 707 final.
improving cooperation between the Member States ‘on the evaluation of risks, alerts, intervention, storage… detection and identification of infectious and toxic agents as well as the prevention and treatment of chemical and biological attacks’. Appointment of a European coordinator for civil protection measures was considered as part of the program. It was stressed that in order to enhance Europe’s capacity ‘to respond to emergencies arising from biological and chemical terrorist attacks,… a mobilization of its research and technology development potential…’, is needed. A joint evaluation of the current knowledge and research capacities should be undertaken.

An inventory on ongoing bio-defence research should be compiled.61 A series of strategies and a ‘road map’ were prepared for making appropriate arrangements for the life sciences. The importance of scientific research was stressed and the commitment to encourage and advance it was underlined. However, it also emphasized that there is an obligation to prevent exploitation of the positive results of this research for malicious purposes.

Within the new Sixth Framework Program for R&D (2002 – 2006), the Joint Center for Research (JRC) was to initiate:

- a bio-response working group….comprising state-of- the- art laboratories…and world experts…to detect and identify relevant transgenic strains…[for] addressing biological attacks to the food chain… to determine the new scientific issues and questions related to bioterrorism and… to assess the technological, social, economic and psychological vulnerabilities of [the] modern societies with regard to possible terrorist attacks. 62

The Council Regulation setting up a Community Regime for the control of exports of dual-use items and technology63, aimed to provide effective control on export of dual use items, has established (in its Annex 1), the common list of dual use items implementing the internationally agreed dual use controls including (among others) the Wassenaar Arrangement and the Australia Group to be updated in conformity with the relevant obligations and commitments.64

1.1.1.4 Conflicts and Controversies in a climate of Uncertainties.

Taking as an example the profusion of existing and amended legal provisions, in the randomly surveyed communities, it should be known that in recent years serious efforts have been made by legislators to control the use and prevent misuse of biological agents. It is to stress that the most severe punishment has been prescribed for malicious uses of biological agents. However, unfortunately it should be remembered that even the severest penal sanction is neither totally deterrent nor preventive. It definitely demonstrates public aversion to such deeds, as also to lesser vio-

61 See id., at para 4.1.
62 See id., para. 4.2.
63 EC Regulation No. 1334/2000 of 22 June 2000, setting up a Community Regime for the control of exports of dual-use items and technology, as amended by EC Regulation 394/2006 of February 27, 2006.
64 See id., Article 1-5.
lent crimes, but it would be naïve to believe that a severe penal sanction is ‘the tool’ for preventing, diverting or deterring monstrosities.

In a post-factum case of employing biological weapons for mass-destruction, enforcement of the penal sanction is entirely abortive, especially in the present trend of suicidal attacks. So while the civilized world is terrified by international terrorism and horrified by ‘clear and present’ dangers stemming from the dual characteristics of certain biological agents – the main concern is to be given to precautionary, preventive, security and safety measures, at their source, to be provided and observed by relevant bodies. This alone is not enough. Judged by the surveyed provisions it shall be said that there is enough legal authority for regulating research in the field of new biotechnology at its source. It may also be said that in many communities there already exists a regulatory framework, providing adequate precautionary bio-safety and bio-security measures for preventing or minimizing recklessness and possible destructive uses of dangerous biological agents. However, as already said, the unprecedented race and advances in biological, biomedical research and technological development, in comparison with the conventional slow pace of the legislative process, make it impossible for the authorized bodies to embrace all the advances, even if speeded up in consequence of recent events. The same is to be said as to updating regulatory implementation regimes and enforcement mechanisms. Thus, it is important to emphasize that awareness and alertness of each individual scientist in dealing with dangerous biological agents and the willingness of the entire scientific community for recognizing the seriousness and feasibility of the possible misuse of biological agents and toxins – is very instrumental. Knowledge, understanding and awareness of the general public is also an important factor in the general effort to prevent, minimize or combat bio-terrorism.

However, ‘negative feedback’ is a known phenomenon. Human nature does not respond to warnings, be it even against the most horrifying atrocities, as were witnessed during WWII. There is apparently an innate human tendency to ignore dangers and to see those as remote and theoretical. 65

Attention is drawn here to the recently announced innovation by a group of scientists in Maryland. The public was informed that they succeeded ‘to build from scratch an entire microbial chromosome, a loop of synthetic DNA, carrying all the instructions that a simple cell needs to live and reproduce’. 66 Craig Venter was quoted saying that ‘the goal is to design novel microbes whose handcrafted genomes endow them with the ability to produce useful chemicals, including renewable synthetic fuels that could substitute for oil’! This definitely stresses the beneficial application of the revolutionary invention, but some of his peers oppose the use of synthetic DNA pronouncing a warning that ‘without better oversight of the fledgling field, synthetic biology is more likely to lead to the creation of potent biological weapons and runaway microbes that could wreak environmental

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65 ‘A man is doomed to destroy himself and at the same time to refuse to believe he is doing so’, See A. MARTIN, The Last Generation. The end of survival? (1975).

66 GIBSON ET AL., supra note 12; see also WEISS, Md Scientists Build Bacterial Chromosome, WASHINGTON POST, January 24, 2008, p. A04.
A Montreal-based group even called for a moratorium on the release and commercialization of synthetic organisms, pending further public debate.\(^{68}\)

Attention is drawn also to the reported efforts to re-create by reverse engineering, old dangerous viruses including the most deadly 1918 flu-virus, or to produce a new type of virus or vaccine, by another new technology. In giving justification to such dealings, the public is informed that these advances in science may give a rapid response to some of the newly emerging dangerous infectious diseases and protect the public from the potentially devastating consequences of a pandemic disease outbreak (\textit{e.g.}, EBOLA and SARS).\(^{69}\) But simultaneously there are also warnings! Such processes pose great unknown risks and must be done in containment in a strictly safe manner, to avoid repetitious disasters!

In addition, the questions are:

1. Should the relevant scientist undertake and proceed in such experimentations just upon his own integrity?
2. Will the public seriously respond to the challenges on these vital controversial issues with their economic, social and moral implications?
3. Should the racing scientist, on his track to future inventions, be the one and only decision-maker in the name of ‘public good’?

Attention is drawn to another controversial case relating to a public warning, which was recently discussed in \textit{Steven J. Hatfill v. The New York Times Co.},\(^{70}\) an offshoot case of the 2001 ‘anthrax disaster’. In describing a series of events preceding the outrageous letters containing anthrax spores, the judgment reveals that in the mid-nineties there were warnings about potential dangers in dealing with anthrax. This was an action for ‘defamation’, commenced in 2004 against the NY Times, following publication in 2002 of a series of columns describing failures of the FBI in its investigation of the anthrax letters. The plaintiff alleged that the columns ‘falsely implicate[d] him in the anthrax mailings… tending to incriminate him….’\(^{71}\) In summing up the merits of the case, the court emphasized that the plaintiff had then (mid 1990s) an established reputation in the field of infectious diseases and bioterrorism research and had a security clearance to work with dangerous pathogens including anthrax. The court stressed that the plaintiff ‘

\begin{quote}
\begin{itemize}
\item took it upon himself to publicize the threat posed to the United States from biological weapons, …
\item In August 1997, [he] provided an interview to a \textit{Washington Times} columnist on the subject of bioterrorism and specifically on the threat of anthrax being used as a weapon… not[ing] that the US health care system was ill prepared for such
\end{itemize}
\end{quote}
an attack. … Plaintiff provided an interview … about the risks of a biological attack and how an anthrax attack could be orchestrated.\textsuperscript{72}

Hatfill, who was considered an experts in the area of biological weapons and agents by government officials and the scientific community alike, propagated increased government vigilance to combat bioterrorism and in 1999 co-authored an article which ‘urged the public health community to step up efforts to be prepared for a chemical or biological attack.’\textsuperscript{73}

In determining the plaintiff’s status, based on the mentioned facts, whether he was a private or a public figure or a public official, the court concluded that he qualifies as a ‘public official’, notwithstanding the plaintiff’s claim that he was a private person, ‘involuntary dragged into the controversial situation’.\textsuperscript{74} The court stressed the fact that the public had an interest in the plaintiff, considering his qualifications, the highly sensitive nature of his work and its importance to national defense. In describing him as ‘a vocal critic of the government’s level of preparedness for a bioterrorist attack’ and in reference to his lectures, writings, participation on panels, and interviews, as well as his own resume as an expert in the field of biological weaponry, the court concluded: ‘The Plaintiff voluntarily assumed a role of special prominence in the public debate over the nation’s preparedness for a biological attack, and indeed sought to influence government policy. The plaintiff should have foreseen that by his activities he ‘was likely to invite [public] attention and scrutiny’.\textsuperscript{75}

Moreover, the relevant questions are: Did his warning really draw attention of the public? Did anybody draw consequences from their contents? Assuming that it was a warning by a recognized expert expressed in classified circles but also on public media, did the decision makers act upon it, and did it raise public concern?

Another offshoot of the anthrax letters was the controversial case of ‘ciprofloxacin’ (‘Cipro’).\textsuperscript{76} It was an example of a controversial issue in a climate of uncertainty that had to be delicately balanced between conflicting interests. On one hand there was the right of a patentee to retain his monopoly on a patented drug, on the other hand was the dilemma whether to enforce or not to enforce government’s statutory right to override patent rights in cases of emergency, and its duty to protect public health and safety, which usually is to prevail, provided it is executed stringently.

\textsuperscript{72} Id., at 524-525.
\textsuperscript{73} Id., at 525.
\textsuperscript{74} As a public official the plaintiff could recover compensation only if the Defendant acted with actual malice in publishing the said columns. Actual malice must be established by clear and convincing evidence. For a private person, the burden of proof is much lesser. See supra note 70.
\textsuperscript{75} Id.
\textsuperscript{76} See RESNIK/DEVILLE, Bioterrorism and Patent Rights: ‘Compulsory Licensure’ and the Case of Cipro, American Journal of Bioethics. 2002 Summer.
An additional controversial issue that recently revisited court was discussed in *Vietnam Assoc. for victims of ‘Agent Orange’ & others v. Dow Chemical Co.*

Plaintiffs, Vietnamese nationals, filed suit against defendants, manufacturers of herbicides, for allegedly causing wrongful death, severe bodily injuries (such as: birth defects, breast and lung cancer, ovarian tumors) and other health problems in result of their exposure to dioxin during the United State’s use of herbicides in the Vietnam War. The plaintiffs alleged violation of international and domestic law in fulfilling the military’s demand for herbicides. They did not allege that the government intended to harm human beings through its use of *Agent Orange*.

In reviewing the history of the herbicide operation that was employed by the US military forces in Vietnam, court relied on the argument by the Defense ministry that ‘one of the most difficult problems of military operations in South Vietnam’ was ‘the inability to observe the enemy in the dense forest and jungle’. It was stressed that the army was instructed to ‘carefully select crop destruction targets… in areas remote from population… [and] only of military significance’. The US government claimed that the 1925 Geneva Protocol does not ban the use of some herbicides in warfare, since ‘chemical herbicides which were unknown in 1925, could not be included within the scope of the prohibitions’. In reviewing the justicibility of the herbicide program the judges emphasized that the operations became a matter of scientific controversy almost from their inception, but the herbicide program was continued because of ‘substantial military benefit’. Court stressed that in April 1970 some components of the herbicide were banned from most U.S domestic uses on the basis of evidence of its ‘possible teratogenicity’. On April 15, 1970, DOD suspended military use of *Agent Orange* upon evidence of toxicity of the dioxin component. In January 1971, the last spray mission took place.

After a lengthy discussion on a diversity of complicated legal issues, the Court concluded that the herbicide spraying complained of did not constitute a war crime in pre-1975. Since *‘Agent Orange* was intended for defoliation and destruction of crops and not as a poison targeting human populations, its use did not violate the international norms….’ The court stressed that: ‘[t]he concept of military necessity or proportionality is a well accepted international norm governing the conduct of war. There is nothing in the UN Charter outlawing the use of herbicides in Vietnam….’

The court observed: ‘Norms that depend on modifiers such as disproportionate or unnecessary, invite case-by-case balancing of competing interests and black-letter rules become vague and easily manipulated.’

One wonders whether *‘Agent Orange’* operation would go on if the US government would have timely applied the ‘precautionary principle’ while the climate was

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77 *Vietnam Assoc. for Victims of ‘Agent Orange’ et al. v. Dow Chemical Co. et al. 517 F.3d 104, 2008 US App. Lexis 3737 (2nd Cir. 2008).*
78 *Id.*
79 *Id.*
of uncertainty which unfortunately became later, a certainty!. One wonders what lesson will be learned from this recent court case?!80

2. Conclusion

All these are very complicated issues, and no clear-cut answer can easily be provided. The ‘delicate balance’ to be found between conflicting interests is not exactly ‘delicate’ in many of these difficult controversial issues. Especially difficult is to find an adequate balance in conflicts between human rights and national or international security. Experienced in adjudication one may dare to say that there is a general universal ‘feel and touch’ in justice, but moral and ethical attitudes that are part of ‘justice’, differ from nation to nation and from person to person, embracing a diversity of considerations, justified by one party and sometimes condemned by another. Thus different vital decisions are reached, also in the adjudicative processes.

Life is full of dangers, most of which are man-created. As already mentioned, science and new technologies enrich humanity, but along with its enrichment, some of the innovative scientific findings or sophisticated technologies often seriously threaten humanity. In extreme cases, there is a posed danger to the well-being of humanity and its survival. Science in its dual capabilities, on the one hand as the benefactor of humanity, and on its other hand as the cause for threats on its survival, is under a heavy responsibility to balance between those capabilities, first within its own boundaries and later in cooperation with other relevant disciplines.

It shall be remembered that in the dynamics of daily life many people are reckless, careless or negligent in performing their chores and legal responsibilities. Some examples thereof are a reckless security guard not identifying a terrorist, a driver recklessly speeding or driving on the wrong side of the road, a medical doctor or a dentist who is careless in performing its duties. Without undermining the severity of such cases, it is to stress that the injury in most of these cases is limited to a certain individual or a group of individuals. But in cases of careless, negligent or wrongful dealing with lethal biological agents, letting those ‘escape’ or be reached by terrorist hands, there is a danger of mass-destruction. Many of the dangerous biological agents are lethal or can genetically be engineered into lethality.

It is usually claimed that all advances in science and technology are for the ‘Public’s Good’, but it is very seldom that the public is consulted or asked to decide on its own good. Although policymakers are supposed to act and represent the public interest, but in practicality this is rarely feasible, especially where there is no normative framework and the issue requires acquaintance with a sophisticated technology in a climate of uncertainties.

Raising awareness and serious concern of laboratory directors, scientists and students in regard to the already existing legal requirements in light of the current bio-terrorist threats, is one of the immediate goals to be undertaken by relevant

80 See also J. Doe, et al. v. L.W. Sullivan Secretary of Health and Human Services, 291 U.S App. D.C. 11; 938 F.2d.1370, 1991 U.S App. Lexis 14984 (D.C. Cir. 1991) (Ruth Ginsberg).
authorities. The ‘precautionary principle’ is to be applied, however any normative framework for preventing, decreasing or minimizing any hostile use or misuse must provide for the undisturbed continuation of scientific research and possibilities of scientific publications, provided these do not diminish the efforts for protecting national security and public health and safety.

It is to think and provide answers and recommendations as to:

1. How can scientific information on controversial issues be framed and communicated by the media, to be best absorbed and seriously received by policy makers, scientists and the general public?
2. What mechanisms can be applied for mediating between expert advice and warnings on risks and dangers and the common tendency of the individual to distance himself from threats and warnings?
3. What criteria shall be applied for resolving conflict of interests and controversies between the utilitarian-economic approach to scientific research, especially now in the field of new biotechnology and other approaches such as political; ethical, moral; social or religious?

Most of the above compiled laws state clearly that ‘nothing… is intended to restrain or restrict peaceful scientific R&D’ and prohibitions on using biological agents do not apply to uses ‘for prophylactic, protective, or other peaceful purposes’. However, it is to bear in mind that in case of conflict, it is only via the adjudicative processes that such rights and exemptions can be enforced. Thus, it is important to observe that many of the clauses speak in a very amorphous language, subjecting it to judicial interpretation of conduct or terms that partly have never been defined.

Although trained in deciding on whatever issue that seeks adjudication, in the rapidly changing global world and highly sophisticated developments in the life sciences, there is a growing gap between scientific expertise and judicial knowledge. There is a need for cross-ventilation between all the relevant disciplines which Professor Straus is practicing in his daily chores.

*No man is an island.* (John Donne, Meditations XVII)