MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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Consideration of the content, promulgation, and adoption of codes of conduct for scientists

BIODEFENCE: CODES OF CONDUCT AND PRACTICE

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1. This paper is intended to provide a reflective exploration of the value of Codes of Conduct/Practice and how they might engage the ethical responsibility of scientists conducting biological research on the thin edge of defensive/offensive military programs. The areas to be discussed include:

i How might a scientist determine where the line between bio-defence and bio-offence exists?

ii How does a researcher know when *the line* between defensive and offensive work has been crossed?

iii If a program or individual were to exceed the boundary, what might be a reporting mechanism?

iv What sort of oversight exists or should exist to track defensive programs?

v Can a code of conduct help in this process?

vi How would it be made effective in a bio-defence context?

The Thin Red Line

2. The *line* between defensive and offensive conversion of information gets thinner by the day. As modern science works with some of the most feared biological agents on the planet,

technologies never imagined are being used to reveal secrets once inaccessible. Because of rapid the advances in biotechnology, defining where defensive application ends and offensive advantage begins is becoming a highly debatable issue. The distance between the two is often clouded by shifting dual-use technological double-talk which clouds the existing threat. The movement, in some cases, can only be categorized by the defining capability of the new technology over what it replaced. In fact every time a biotechnology enables new changes in genotypic or phenotypic character, morphology or amplification characteristics, the *line* moves. The question is do we define the *position of the line* by the revelatory power of the technology, by the data generated or both?

3. If the former, then every time a new technology is fielded, its ability (potential) to provide offensive information must be assessed and if that capability exists, what then? The logic leads to difficult and controversial conclusions. If the latter is used to define the cross-over area, then scientific censorship robs the scientific community of its curiosity and intellectual freedom. Where the *line* may lie is perhaps easier to spot by asking a basic question every qualified biological researcher (and possibly the more informed public) can answer without the need of exhaustive "word smithing". The question is; where do we not want to go? (Admittedly, researchers sometimes end up in a place totally unexpected).

4. This will vary with the nature of the work but perhaps is definable by key words and phrases like *; environmental persistence, resistant to, highly virulent, shortened incubation period, modification or down regulation of the immune response, no immunity to, ease of production, ease of dissemination, very stable, not seen in nature before.* It takes little scientific imagination for an experienced investigator to see and understand the short distance to an offensive application when characteristics like increased virulence, high environmental persistence or antibiotic resistance have been altered. In the course of a program, these findings should give immediate pause to all doing the work. However, in today's political and scientific climates, many states programs lack the *will* to assure a defensive/offensive review of the work. With this existing problem, how can this be accomplished?

5. First, a *compelling need* to establish a review process must come from the public and scientific communities. Commonly this happens after a catastrophic event followed by a timely political and public outcry. Fear often establishes the ground for a *new culture*. The *new culture* then begins the work of raising the level of sensitivity to the threat through methods like, education, assessment, guidelines and persuasion. Although many will resist *another process* placed on their existence (read… more bureaucracy), self-policing will not guarantee the transparency and accountability needed to satisfy and protect the public and environmental welfare.

Crossing the Line

6. Scientifically, crossing *the line* can be interpreted many ways. It may be a journey into a world unimagined and more often today, a world unexpected. Pearson and Dando write:

> *Historically biodefence has been subject to competing interpretations about the acceptability and definition of various activities justified for protective measures. Few have advocated a complete halt to such activities.....Yet the potential for defensive projects to further offensive capabilities (in terms of knowledge, techniques or the availability of*

materials) has led some to express unease....about taking part in biodefence work. Even within the biodefence community, there has been some recognition of the need to ask questions about the ends that might be served (however inadvertently).[1]

7. This *questioning of motives* has generally not resonated as well within the non-biodefence community as it has within military spheres as evidenced by the open publication several papers with potential offensive applications. There is a public perception that weapons based applications only come from military programs. This is not entirely true as much of the leading edge biological work having weapons applications comes out of civilian programs.

8. Pearson and Dando go on to write that determining where the line between acceptable and unacceptable research lies is subject to competing views (1). As discussed earlier, the *line* is continually shifting which (according to these authors and others) makes knowing when one enters into "no mans land" a technical and ethical challenge. Technical or ethical establishment of the boundary inevitably leads to polarized arguments and loopholes. How then can accountability and dependable judgment be exercised by the investigator whose duty it is to examine and follow the data to its logical end and application.

9. Can history give us some guidance? Yes. Treaties have been created to stop the production, retention, delivery of biological materials not intended for peaceful purposes. However recent examples with clear offensive potential in the data and methodologies have been published (i.e. Chemical Synthesis of Polio cDNA: Generation of Infectious Virus in the Absence of a Natural Template Cello et al., 2002, Variola virus immune evasion design: Expression of a highly efficient inhibitor of human complement. Rosengard et al., 2002).

10. In the February 6, 2004 edition of Science, it was reported that two teams of researchers, led by John Skehel, National Institute Medical Research London and Ian Wilson of the Scripps Research Institute in San Diego had managed to synthesize the haemagglutinin protein responsible for the 1918 outbreak of Spanish flu by piecing together DNA procured from a lung sample taken from the body of an Inuit woman buried in the Alaskan tundra and a number of preserved samples taken from American soldiers of the First World War. The two teams had analyzed the structure of the gene and discovered how subtle alterations to the shape of a protein molecule had allowed it to move from birds to humans with such devastating effects.[2] Although these examples did not come from weapons programs nor where they intended as such, the ominous portent of the data is apparent.

11. Whether modifying a virus to make it highly virulent or, synthetically re-constructing a highly virulent and "reportable virus", the majority of researchers know where this can lead and should turn on an amber or red light. Ethical accountability should discern the potential harm and outcome. The investigator must question whether they have or are about to breach the BTWC or other relevant conventions. As such, knowledge of all relevant treaties and agreements is essential to an investigator. They must ask if the methods and data generated by their research were released into the open literature, what impact would it have on global security, public safety

[1] Graham S Pearson, Malcolm R Dando. Strengthening the Biological Weapons Convention. Briefing Paper 13 (Second Series) Towards a Life Sciences Code: Countering the Threats from Biological Weapons
[2] Science Daily. http://www.sciencedaily.com/encyclopedia/spanish_flu

and health, environmental health and the political balance in a national and global context. Would it have direct offensive military application and advantage?

12. Will investigators always make *the right* decision? Probably not, until a new defended culture aimed at eliminating this threat emerges.[3]

Tracking Programs and Reporting Offensive Work

13. Tracking and reporting data or methods with potential offensive applications is only effective when *preclusion* is an acknowledged ethic within the political climate and managerial mandate supporting them. Without a "buy-in" from senior political and management levels, *whistle-blowing* is seen as a breach of trust and loyalty by government, academia and private industry, subject to punitive action. The fear created is often enough to prevent many investigators and managers from reporting offending research. Effective tracking, if it is to work, operates at the bench level with upper-level support and oversight. Regrettably, in some cases, management will not "buy-in", leaving some investigators in an ethical dilemma, agonizing over their silence and fearful of personal reprisal.

14. With a management buy-in, how might tracking and reporting occur?

15. The keystone to open reporting is the establishment of a trusted institutional body to which concerns can be communicated. The body could be a committee of the senior responsible manager (SRM) yet operate at arms length from managerial interference. At the institutional level, this might consist of an expert panel familiar with all programs and any science under review (panel members involved with the work should be excluded from deliberation). Protocols would be reviewed against a clear set of guidelines (i.e. Code of Ethics on Offensive Research) and report to the SRM. The Code could consist of a nationally agreed to set of guidelines considered core to every institute conducting microbiological research and integrated with specific institutional requirements that facilitate effective program oversight. This report would then be acted on and reported to a national leadership and monitoring body. The National monitoring body should be at arms length from any groups having influence or vested interest in them or in any of the user groups being monitored (government, academia and industry).

16. In Canada at present, the monitoring body currently overseeing defensive biological/chemical research in the military is the Biological Chemical Defence Review Committee (BCDRC). While the threat from such weapons endures, Canada has an obligation to ensure that members of the Canadian Forces (CF) have adequate training and equipment to protect themselves against exposure to chemical and biological agents.

17. Additionally, the Canadian public has the right to be assured that Canada's policy of maintaining only a defensive capability in this field is fully respected at all times, and that any research, development and training activities undertaken pose no threat to public safety or the environment (3).

[3] Amy E Smithson. Biological Weapons: Can Fear Overwhelm Action?

18. The BCDRC annually visits Defence R&D Canada - Suffield (DRDC Suffield); Defence R&D Canada - Toronto (DRDC Toronto), the Canadian Forces Nuclear Biological and Chemical (CFNBC) School and at least two other DND Establishments where biological and chemical training is conducted.

19. It reviews the annual DND Research and Development Program as originated by the Assistant Deputy Minister Science and Technology (ADM S&T) and approved by the Defence Management Committee.

20. It reviews the implementation of the recommendations made in the BARTON REPORT of 31 December 1988 and the 1992 Independent Environmental Audit of DRDC Suffield and previous BCDRC Reports. It examines the DRDC Suffield and Defence R&D Canada - Toronto (DRDC Toronto) Annual Reports, activities and records of the Human Research Ethics and Animal Care Committees and the current research and development contracts and publications lists.

21. The BCDRC then submits a report of their activities and findings to the Chief of the Defence Staff (CDS) and the Deputy Minister (DM) of National Defence.[4]

22. The Committee, consisting of a chairperson and two members representing the disciplines of chemistry, microbiology and toxicology, is appointed for three years by the DM/CDS on the recommendation of the pertinent learned societies and the Committee Chairperson. Additional information can be found in the August 2003 paper of the BTWC, Canada's Biological and Chemical Defence Review Committee: Transparency Model.

23. A body similar to the BCDRC could give national review and oversight and where required, arbitrate inconclusive or contentious reviews.

Codes of Conduct

24. Codes of Conduct provide a guideline for optimal thought and behaviour, setting out the spirit of, and aspiration to a standard. Codes of Practice, although integrally related and arguably synonymous, point to the proscriptive or regulatory activity of a superintending body. Both provide a systematic collection of consistent unambiguous guidelines that support a standard of moral or ethical behaviour within a defined group. They directly state the intent of a group to adhere to a defined *culture and norm*. However as mentioned, they only work when a *100% upper level "buy-in"* occurs, that is; when management and their political masters are ready to *count the cost* of a Codes defence in supported by *education and assessment programs that directly feed back divergences, alternative solutions, affirmation and reward*. If the clarity, force and support required to administer a Code of Conduct or Practice is equivocal, it will never withstand the pressures that inevitably will confront it.

25. An example of this problem is current state of the WHO and its eroding position on the destruction of smallpox stocks. With mounting political pressure from some member states bent on continuing small pox research, the World Health Assembly (WHA) has moved from a

[4] The BCDRC Website http://www.vcds.forces.gc.ca/bcdrc/intro_e.html

destruction to retention to limited research and finally, to allowing specified genetic modification of smallpox. It is the *one brick at a time* dismantlement of agendas that Codes must withstand.[5] The *"will"* to accomplish and sustain their purpose must be resolute if they are to succeed!

26. The question then is whether a Code of Conduct or Practice helps or hinders the process of defining when a program or investigator *crosses the line* into the area of biological offensive research. The answer is again yes if the afore mentioned criteria can be accomplished.

27. So what would this Code look like and how might it operate? As mentioned earlier, it must start with individual accountability, because as the individual goes, so go societal norms. Every person is a small reflection of a collective spectrum of societal norms. Public perception forms a reality directly linked to the collective norm. Therefore a vision of the *new culture and its norm* must be cast in the collective public and scientific mind defining its purpose, goals and particularly its ethical sensitivity. It is important that the goals not be unrealistically ambitious. Much of the current literature describes overly ambitious Codes of Conduct that aim for global universality without elucidating local and national infrastructures. Although the "big picture" is important, the process must start at the local level and work up. In this case, the issue is so politically charged, creation of a *new culture* and supportive Code is a generational work.

28. An example of this process has been the emergence of the body overseeing the use of experimental animals in Canada. In 1963, the Medical Research Council (MRC) requested that the National Research Council (NRC) establish a Committee to investigate the care and use of experimental animals in Canada. In 1968, according to the Committee's recommendation to create a voluntary control program exercised by scientists in each institution, subject to peer review and committed to implementing the guiding principles of an independent advisory body, the Canadian Council on Animal Care (CCAC) was established.

29. Its mission statement underlines the focus of the CCAC on the ethical principles of animal-based experimentation.[6] Forty-three years later and the CCAC is still working at establishing regional and national universality. Their definition of universality started with the individual and works toward capturing the greater user groups. Universal application of the CCAC programs means they apply to all animals used by: I) individuals, ii) members and iii) employees, agents or owners acting on behalf of organizations or businesses registered or operating in Canada.

30. "The purpose of the CCAC is to act in the interests of the people of Canada to ensure, through educational, assessment and guideline programs, animal use when necessary, employs optimal physical and psychological care according to acceptable scientific standards. Additionally the CCAC promotes an increased level of knowledge, awareness and sensitivity to "relevant ethical principles". The CCAC has withstood many challenges by adhering unequivocally to its vision and mandate over the years. Today it is a well respected body both in Canada and around the world, recognized for its educational and protective role in the use of experimental animals.

[5] Third World Network. The Genetic Engineering of Smallpox. www.smallpoxbiosafety.org
[6] The Canadian Council on Animal Care. Website www.ccac.ca

31. Has the Code of Ethics established by the CCAC helped Canadian research in the use of experimental animals? Yes! It has provided every institutional Animal Care Committee the foundation for their over sight of animal use and the confidence to act authoritatively and fairly when necessary.

A Code within the Biodefence Context

32. A Canadian model of a Microbiological Code of Practice could operate (using the CCAC model) by first establishing oversight at the local level. By incorporating *ethical* and risk assessments of proposed microbiological work within existing institutional body doing similar work, the mission and goals could be harmonized. A national oversight body integrated into an existing national structure with related duties would likewise harmonize resources and act to give guidance and authority to the locally established committees.

33. As an example, within the Defence Research Unit at Suffield, the Biohazard Safety Committee examines by a specific process all proposed Chemical and Microbiological studies through an established study approval procedure. It incorporates approval of an animal care protocol by the local Animal Care Committee which, in its deliberations, considers the ethical use of the animals under the CCAC guidelines but also seek proof of the scientific merit and its impact on the current body of scientific knowledge it addresses. In addition, the process covers any Human Ethics considerations along with chemical and biological safety issues. The biological safety addresses the aim of the study, the agents to be used in particular the name, strain, whether live or dead, concentration, source, and the amount needed for the study. It identifies the site(s) of use, safety measures, the organism risk levels 2-4, use of controlled substances which include prescription drugs, anesthetics and any other chemicals. Removal and use of any DNA (risk level-3 agents) with subsequent use and disposal must be described. Included with this is a detailed description of the protocol. Here then exist two places where integration of an ethical review of the defensive/offensive implications of a protocol could be effectively carried out. This could be done under a nationally established Code of Conduct and Practice and implemented at the local level by a committee of experts mandated under National authority. Their mandate would be to ensure that research activities involving microbiological agents or toxins whatever their origin or method of production are only of types and in quantities that have clear and unequivocal use and justification for prophylaxis, protection and other peaceful purposes.

34. At the national level, a committee such as the BCDRC which is directly involved with this mandate could have an attached “arms-length” expert group which would be the leadership and assessment group. The National body would have national representation from both the technical and professional levels thus providing peer-based representation from all levels of the scientific community.

35. The life and culture of the organization would be sustained by core guidelines, education, peer-based assessment and persuasion. The goal, over time, would be national acceptance and participation in an oversight program. The value of participation would be the accountability of the individual scientist and manager, occupancy of a defined ethical “high ground”, public perception of legitimacy and accountability (locally, nationally and globally) and perhaps most importantly, the creation of an new culture that safeguards people and the environment.

Conclusions

36. This paper has reflected in direct and basic terms what may be involved in constructing within the greater scientific community a newly sensitized and cooperative culture dedicated to deterring the knowing development of offensive biological research programs and the dispersion of data and methods from those efforts. The recognition of the cross-over area between defensive and offensive application is sometimes difficult because of the speed of technological advances and the failure of the scientific community to fully rationalize the impact. However it may be of some value to use recognized benchmarks most scientists quickly rationalize and commonly interpret individually and corporately. Those are the terms that describe major changes in the cultural or genomic characteristics of an organism and give it its genus and species capabilities regarding survival, infectiousness, virulence, replication, incubation period and resistance to its environment.

37. Reporting program research that may have knowingly or unwittingly ventured into the offensive arena is dependent on trust and the backing given by senior managers and politicians to assure confidence to those needing to communicate concerns. Without a 100% buy-in and defence of the reporting and review mechanism within a research institute, effective leadership and oversight will fail. Finally, the efforts to establish an effective mechanism to review ongoing program science must be structured locally with a national leadership body. Both bodies could be integrated with existing bodies at their respective levels carrying out similar function in order to harmonize effort and resources. An structural example might be a BCDRC model. On going review and oversight would be based on evolving guidelines, education and peer-based assessment both locally and nationally. Unequivocal dedication to the core principles, mission and goals is central to success.

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