IV. Oversight of dual-purpose research in the life sciences

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Russian–US cooperation in the life sciences

In June 2013 the 1992 Russia–United States Umbrella Agreement for the Cooperative Threat Reduction (CTR) programme lapsed.[1] The focus of CTR in recent years, as well as that of the Group of 8 (G8) Global Partnership against the Spread of Weapons and Materials of Mass Destruction, has been on biological threat reduction.[2] In the US budget for financial year 2014, 'biological weapons engagement programs' represented just under 60 per cent of the CTR budget, while biothreat reduction was signalled as an area of interest by the G8 at a meeting in Stockholm, Sweden, in 2012.[3] On 26–28 September 2013 former CTR programme participants and scholars met at St Simons Island, Georgia, USA, to discuss and analyse the results of the CTR programme.[4]

Russia also indicated that it plans to end its work with the internationally funded International Science and Technology Center (ISTC), whose mandate is to help ensure that scientists with dual-purpose expertise remain usefully employed rather than conduct work in support of possible weapon programmes. In February 2013 an expert Russian–US panel recommended that the two countries jointly fund life sciences research.[5]

Discovery of a new botulinum neurotoxin

In October 2013 the *Journal of Infectious Diseases* published two papers describing a new strain of *Clostridium botulinum*, isolated from a child with infant botulism, which produced a previously uncharacterized botulinum neurotoxin. The first paper described the production of the neurotoxin, BoNT/H, which was produced together with type B neurotoxin and could

[1] Woolf, A. F., Kerr, P. K. and Nikitin, M. B. D., *Arms Control and Nonproliferation: A Catalogue of Treaties and Agreements*, Congressional Research Service (CRS) Report for Congress RL33865 (US Congress, CRS: Washington, DC, 15 July 2013), p. 21. On the end of the CTR see also chapter 7, section III, in this volume.

[2] As of Jan. 2013 there were 25 members of the Global Partnership: Australia, Belgium, Canada, Czech Republic, Denmark, the European Union, Finland, France, Germany, Ireland, Italy, Japan, Kazakhstan, Mexico, Netherlands, New Zealand, Norway, Poland, Russia, South Korea, Sweden, Switzerland, Ukraine, the United Kingdom and the USA.

[3] Woolf et al. (note 1), pp. 22, 26.

[4] Blanton, T., Savranskaya, S. and Melyakova, A. (eds), 'Nunn–Lugar revisited', National Security Archive Electronic Briefing Book no. 447, George Washington University, 22 Nov. 2013, <http://www2.gwu.edu/~nsarchiv/NSAEBB/NSAEBB447/>.

[5] Committee on US–Russia Assessment of Bioengagement Development, Security, and Cooperation, *The Unique U.S.–Russian Relationship in Biological Science and Biotechnology: Recent Experience and Future Directions* (National Academies Press: Washington, DC, 2013).

not be neutralized using available monovalent polyclonal botulinum antitoxins provided by the US Centers for Disease Control and Prevention in Atlanta, Georgia.[6] The subsequent second paper explained how the researchers sequenced the neurotoxin gene cluster of the novel strain (IBCA10-7060) and confirmed it as distinct from previously characterized botulinum neurotoxin types.[7] It had been 40 years since the discovery of a new botulinum neurotoxin.[8]

As the authors, who were US-based, were aware that current antitoxins are unable to neutralize type-H botulinum neurotoxin and that this new knowledge was most likely unknown to others, they consulted with US officials and chose not to submit the sequence data to GenBank—a US public repository of nucleotide sequences—until an effective antitoxin has been developed.[9]

In an editorial in *The Journal of Infectious Diseases*, Stanford University's David A. Relman, a member of the US National Science Advisory Board for Biosecurity, wrote: 'Until anti-BoNT/H antitoxin can be created, shown to be effective, and deployed, both the strain itself and the sequence of this toxin (with which recombinant protein can be easily made) pose serious risks to public health because of the unusually severe, widespread harm that could result from misuse of either.'[10]

Relman also referred to a 1980s study by the US National Academy of Science's Panel on Scientific Communication and National Security, which examined the growing discourse between scientific openness and national security concerns.[11] The panel identified 'grey area' research activities, which should not be classified but restricted. To fall in this category, the following criteria all have to be met: (*a*) research with dual-use or military applications, (*b*) research with a short time to such applications, (*c*) research where dissemination could give short-term advantage to adversaries, and (*d*) research where the information was believed not to be

[6] The letter 'H' was used as it was the 8th characterized botulinum neurotoxin. Previously characterized botulinum neurotoxins are A, B, C1, C2, D, E, F and G. Barash, J. R. and Arnon, S. S., 'A novel strain of *Clostridium botulinum* that produces type B and type H botulinum toxins', *Journal of Infectious Diseases*, vol. 209, no. 2 (Jan. 2014), pp. 183–91.

[7] Dover, N. et al., 'Molecular characterization of a novel botulinum neurotoxin type H Gene', *Journal of Infectious Diseases*, vol. 209, no. 2 (Jan. 2014), pp. 192–202.

[8] Popoff, M. R., 'Botulinum neurotoxins: more and more diverse and fascinating toxin proteins', *Journal of Infectious Diseases*, vol. 209, no. 2 (15 Jan. 2014), pp. 168–69.

[9] Among the US federal agencies consulted were the Army's Infectious Diseases Laboratory, the Department of Homeland Security and the Centers for Disease Control and Prevention. GenBank, 'GenBank overview', <http://www.ncbi.nlm.nih.gov/genbank/>. See also MacKenzie, D., 'New botox super-toxin has its details censored', *New Scientist*, 14 Oct. 2013.

[10] Relman, D. A., '"Inconvenient truths" in the pursuit of scientific knowledge and public health', *Journal of Infectious Diseases*, vol. 209, no. 2 (7 Oct. 2013). His comments referred to Arnon, S. S. et al., 'Botulinum toxin as a biological weapon: medical and public health management', *Journal of the American Medical Association*, vol. 285, no. 8 (28 Feb. 2001), pp. 1059–70.

[11] Panel on Scientific Communication and National Security et al., *Scientific Communication and National Security* (National Academy Press: Washington, DC, 1982).

already held by adversaries.[12] Relman highlighted this 'grey area' and stated that: 'The authors of these articles, believing that the sequence information of BoNT/H poses an immediate and unusually serious risk to society, and that the information was unlikely to be already in the hands of those who would seek to do harm, decided to exercise voluntary prepublication control and to withhold this specific information.'[13]

Reproduction of DNA

In an interview in October 2013, J. Craig Venter—a prominent US biologist and founder of several companies that focus on gene sequencing and synthesis work—discussed a current project for downloading and sharing DNA information for reproduction by so-called digital biological converters. Such converters are the biological equivalent of three-dimensional (3D) printers. Venter has also characterized life as 'DNA software driven'.[14]

The eventual widespread use of 3D printers has the potential to make some non-proliferation efforts less relevant, including those aimed at the consolidation of pathogen strains at a small number of facilities with high levels of security and oversight efforts to ensure that traditional pathogen strain sharing by post is done for peaceful purposes only.

[12] Panel on Scientific Communication and National Security et al. (note 11).

[13] Relman (note 10).

[14] Interview with J. Craig Venter, *Charlie Rose Show*, 21 Oct. 2013, <http://charlierose.com/watch/60285321>. See also Venter, J. C., *Life at the Speed of Light: From the Double Helix to the Dawn of Digital Life* (Viking: New York, 2013).