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For the attention of:

22 October 2014

Samuel L Stanley
Chair, National Science Advisory Board for Biosecurity (NSABB)

An open letter to the NSABB challenging potentially dangerous 'gain of function' research

Dr Stanley

Re [the upcoming NSABB meeting to discuss controversial 'gain of function' research](#), to be held on 22 October 2014.¹

As a global citizen, I wish to register my opposition to lab-engineering of potentially lethal pathogens being sponsored by the United States Government and other parties.

There appears to be seriously inadequate ethical oversight of this dangerous research, which may be taking place around the world in an unknown number of facilities in universities, research laboratories and pharmaceutical companies.

It is most concerning that there is an arrogant attitude about this type of research in the scientific community, perhaps exemplified most tellingly in the comments of Vincent Racaniello, Professor of Microbiology and Immunology in the College of Physicians and Surgeons of Columbia University.

In an interview re controversial influenza H7N9 gain of function experiments², [broadcast on Dispatch Radio in August 2013](#)³, Professor Racaniello stated:

*So a **'gain of function'**⁴ simply means that you take a virus and you change it in some way **so it does something new, so it does something that it didn't do before.** That's all that means. It's quite simple. **So you could for example take this H7N9 virus and make it resistant to an anti-viral drug, that would be a gain of function...***

*So, to really understand how this virus works, and really any other virus, **we do gain of function studies all the time. We don't make a big deal of it, we don't write letters telling the world that we're going to do them because that's not the way science works. Science works by just doing your experiments.*** We do this because we would like to see what kinds of changes would lead to a gain of function, and what would be the consequences.

*So, in the case of this virus, **these investigators want to make the virus drug resistant.** As you know, there are a couple of anti-virals that you can use if you get influenza – Tamiflu, Relenza - **and these investigators want to make the virus resistant. And the reason they want to do that is to see if a drug resistant mutant would have any properties that would make it scarier in people.***

*So there is really a goal to these experiments. They want to know if you change the virus what might be the consequences for people. **And as I said this is done all the time but these virologists decided to tell the world about it.***

(My emphasis.) ([Full transcript of interview attached to view comments in context.](#))

Professor Racaniello says **"we do gain of function studies all the time. We don't make a big deal of it, we don't write letters telling the world that we're going to do them because that's not the way science works. Science works by just doing your experiments."** Professor Racaniello seems to infer that it is acceptable for scientists to manipulate viruses, e.g. make a **"virus drug resistant...to see if a drug resistant mutant would have any properties that would make it scarier in people"** without telling **"the world about it"**. (I challenged Professor Racaniello about his comments on his Virology blog post ["Virologists plan influenza H7N9 gain of function experiments"](#)⁵, but he did not respond.)

I suggest Professor Racaniello's attitude is arrogant and irresponsible.

How many other scientists are undertaking this type of research “without telling the world about it”, and with scant regard for potentially disastrous consequences? For example, are scientists manipulating the ebola virus to “make it scarier in people”?

As well as scientists manipulating potentially deadly pathogens with little or no effective ethical oversight, careless practices are also a serious problem in some laboratories. [A CIDRAP report on lab biosafety](#) refers to **“recent incidents in which lab workers at the Centers for Disease Control and Prevention (CDC) inadvertently sent potentially viable *Bacillus anthracis* samples to a low-containment lab and shipped nonpathogenic avian flu virus samples contaminated with the deadly H5N1 virus to a US Department of Agriculture lab. Those mishaps were followed by the discovery of smallpox virus samples in a Food and Drug Administration facility”**.⁶

Following these significant lapses in biosafety and biosecurity at US Federal research facilities, [The White House Office of Science and Technology Policy advises](#) the US Government **“has taken a number of steps to promote and enhance the Nation’s biosafety and biosecurity, including immediate and longer term measures to review activities specifically related to the storage and handling of infectious agents”**.⁷

It has also been announced that [there will be a pause in US Government funding](#) of any new studies involving gain of function experiments with influenza, SARS, and MERS, and a ‘deliberative process’ is being launched to assess the potential risks and benefits associated with gain of function research.⁸ The NSABB and the National Research Council (NRC) of the National Academies will be involved in this deliberative process, [commencing with a NSABB meeting on 22 October 2014](#).⁹

Francis S Collins, Director of the National Institutes of Health, notes that **“public involvement in this deliberative process is key, and the process is thus designed to be transparent, accessible, and open to input from all sources”**. Dr Collins encourages us to **“follow these deliberations closely”**.¹⁰

I hope that Dr Collins is paying more than lip service to the notion that **“public involvement in this deliberative process is key”**. **Sponsoring of potentially dangerous gain of function research, and mishandling of pathogens, are matters of serious concern for global citizens. Discussion on these matters should not be restricted to scientists and bureaucrats with possible conflicts of interest.**

In regards to ‘public involvement’ in this matter, I have sought to make submissions previously, ie:

- In January 2012 I forwarded [an open letter to the NSABB](#) re the political and ethical implications of lethal virus development to Dr Paul Keim, then Acting Chair of the NSABB, and Dr Michael Osterholm, then a member of the NSABB. Beyond acknowledgement of receipt of my letter, I received no further response to the important matters raised, e.g. **my suggestion that by sponsoring development of a potentially lethal flu virus, the United States could be in breach of the Biological Weapons Convention**. Please see attached [my letter to Dr Keim](#) for further background.
- In December 2012 I made [a submission to the Centers for Disease Control and Prevention \(CDC\), Department of Health and Human Services \(HHS\)](#) re my opposition to lab-engineering of potentially lethal pathogens, also attached.

I request that the recently revised NSABB membership consider this submission, and my previous submissions as detailed above and attached, in the deliberative process for gain of function research. I also question what processes are being put in place to allow interested parties such as myself to be kept abreast of developments on this matter, e.g. email updates?

Sincerely
Elizabeth Hart

Please note this letter will be forwarded to other parties for information, including the cc list below

cc:

- Francis S Collins, US National Institutes of Health
- Anthony Fauci, US National Institute of Allergy and Infectious Diseases
- Ralph J. Cicerone, US National Academy of Sciences

- Paul Keim, past Chair of the NSABB
- Michael Osterholm, past member of the NSABB
- Vincent Racaniello, Columbia University
- Ron Fouchier, Erasmus MC
- Ab Osterhaus, Erasmus MC
- Yoshihiro Kawaoka, University of Wisconsin-Madison
- Marc Lipsitch, Harvard School of Public Health
- Peter Palese, Mount Sinai School of Medicine
- Tom Jefferson, Cochrane Vaccines Field
- Peter Gøtzsche, The Nordic Cochrane Centre
- Lord Robert May, Oxford University
- Philip Campbell and Declan Butler, *Nature*
- Caroline Ash and Martin Enserink, *Science*
- Fiona Godlee and Deborah Cohen, *British Medical Journal*
- Brian Martin, University of Wollongong
- Bea Mies, Independent Vaccine Investigator
- Monika Peichl, Independent Vaccine Investigator
- Carolyn Mosby, National Institutes of Health

References: (Links and hyperlinks active as at 22 October 2014.)

¹ Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research. Issued by The White House Office of Science and Technology Policy. 17 October 2014: <http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research>

² The interview was about the proposed gain of function experiments on H7N9, which were discussed in a letter by Ron A.M. Fouchier, Yoshihiro Kawaoka and 20 co-authors, published in [Nature](#) (*Nature* 500, 150-151, 8 August 2013) and [Science](#) (*Science* 9 August 2013: Vol. 341 no. 6146 pp. 612-613).

³ Vincent Racaniello spoke with Robert Herriman, executive director of The Global Dispatch, about the proposed avian influenza H7N9 virus gain of function experiments on Dispatch Radio, August 2013:

<http://www.virology.ws/2013/08/13/influenza-h7n9-gain-of-function-experiments-on-dispatch-radio/> I have also prepared a transcript of this interview which can be accessed via this link:

http://users.on.net/~peter.hart/Racaniello_GOF_transcript_10_August_2013.pdf

⁴ Screen shot of Vincent Racaniello's description of 'gain of function', i.e. it "...simply means you take a virus and you change it in some way so it does something new... something that it didn't do before."

<http://users.on.net/~peter.hart/Gain%20of%20function%20Racaniello.PNG> as depicted in Professor Racaniello's interview on Dispatch Radio: <http://www.virology.ws/2013/08/13/influenza-h7n9-gain-of-function-experiments-on-dispatch-radio/>

⁵ Virologists plan influenza H7N9 gain of function experiments. Published on virology blog, 7 August 2013:

<http://www.virology.ws/2013/08/07/virologists-plan-influenza-h7n9-gain-of-function-experiments/>

⁶ More voices call for action on lab biosafety. (Robert Roos). CIDRAP. 31 July 2014: <http://www.cidrap.umn.edu/news-perspective/2014/07/more-voices-call-action-lab-biosafety>

⁷ Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research. Issued by The White House Office of Science and Technology Policy. 17 October 2014: <http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research>

⁸ *Ibid.*

⁹ More information about the NSABB meeting to be held on 22 October, including a hyperlink to the draft agenda, is accessible via this link: <http://osp.od.nih.gov/office-biotechnology-activities/event/2014-10-22-121500-2014-10-22-200000/nsabb-meeting>

¹⁰ Statement on Funding Pause on Certain Types of Gain-of-Function Research. Issued by Francis S Collins, Director, National Institutes of Health. 17 October 2014: http://www.nih.gov/about/director/10172014_statement_gof.htm