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An open letter to the NSABB re the political and ethical implications of lethal virus development

For the attention of:

Paul Keim, Acting Chair, National Science Advisory Board for Biosecurity

Please note this letter and your response will be forwarded to other parties for information.

cc: Michael Osterholm, NSABB
Ron Fouchier, Erasmus MC
Ab Osterhaus, Erasmus MC
Yoshihiro Kawaoka, University of Wisconsin-Madison
Peter Palese, Mount Sinai School of Medicine
Tom Jefferson, Cochrane Vaccines Field
Philip Campbell, *Nature*
Caroline Ash, *Science*
Deborah Cohen, *British Medical Journal*

Dr Keim

Further to our previous correspondence on the controversial topic of 'lethal flu virus' development.

Please accept this open letter as a layperson's perspective on this topic.

Ron Fouchier and Ab Osterhaus [have questioned](#) "whether it is appropriate to have one country, i.e. the United States, dominate a discussion that has an impact on scientists and public health officials worldwide".¹

I am astonished at the naiveté of these scientists. Surely it must be obvious by now that by sponsoring development of a potentially lethal flu virus the United States could be in breach of the [Biological Weapons Convention](#)², which entered into force in March 1975, i.e.

Article 1 of the Convention states:

Each State Party to this Convention undertakes never 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;

¹ Preventing pandemics: The fight over flu. *Nature* (2012). Published online 15 January 2012:
<http://www.nature.com/nature/journal/vaop/ncurrent/full/481257a.html>

² Biological Weapons Convention (BWC). Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and On Their Destruction. Entered into force March 26, 1975:
<http://www.armscontrol.org/treaties/bwc>

Can it be argued that development of a lethal flu virus is justified for “prophylactic, protective or other peaceful purposes”? **I suggest this is highly questionable.** For instance Thomas V. Inglesby, Anita Cicero, and D.A. Henderson say: “We are not opposed to research in high-containment labs using dangerous pathogens, including H5N1. Over the past decade, the Center for Biosecurity has publicly argued for the importance of such research to develop diagnostics, medicines, and vaccines for the most threatening infectious diseases. **But research and development for those purposes does not require engineering lethal viruses to make them more transmissible between humans.”³**

In *Foreign Policy*⁴, Laurie Garrett describes U.S. Secretary of State Hillary Clinton's surprise visit to the review summit on biological weapons in Geneva in December last year, saying that Secretary Clinton warned of al Qaeda's call to arms for “brothers with degrees in microbiology or chemistry to develop a weapon of mass destruction”.

It is interesting that Secretary Clinton deflected concern about the development of biological weapons onto al Qaeda, **while it is actually the U.S. that is actively involved in sponsoring the development of lethal flu viruses.** I wonder if this irony was lost on other signatories⁵ to the Biological Weapons Convention, such as Iran and Pakistan?

What position would the U.S. take if countries such as Iran and Pakistan sponsored lethal virus development?

Dr Fouchier has announced his team “mutated the hell out of H5N1”, and warned that “this is a very dangerous virus”.⁶ His claims must be subjected to scrutiny. There are doubts as to whether the flu virus developed in the Erasmus MC laboratory is indeed as deadly to humans as we've been led to believe. (See for example a paper by Peter Palese and Taia Wang: *H5N1 influenza viruses: Facts, not fear*⁷).

Regardless of whether the Erasmus MC developed virus is lethal to humans or not, **the question remains whether it is legitimate for any party to sponsor the development of lethal viruses?**

Perhaps if the controversial flu virus research studies conducted by Erasmus MC and the University of Wisconsin-Madison had undergone an effective ethics approval process we would not be in the unfortunate position we are in now?

In his discussion of *Governance of dual-use research: an ethical dilemma*⁸, bioethicist Michael Selgelid describes the conflict between the voluntary self-governance of the scientific community, and the security concerns of bureaucrats and security experts. Selgelid notes that “most of the debates about the dual-use dilemma have primarily involved science and security experts rather than ethicists”. Selgelid argues that “biological weapons development may turn out to be one of the most serious consequences of the genetics revolution in biology”. He concludes: “It is thus crucially important that there is more ethical input into debates about the governance of dual-use research.” Selgelid's paper was published in 2009. Given the current controversy, it appears his warning fell upon deaf ears.

³ Editorial by Thomas V. Inglesby, Anita Cicero, and D.A. Henderson. The Risk of Engineering a Highly Transmissible H5N1 Virus. Center for Biosecurity of UPMC. 15/12/2011: <http://www.upmc-biosecurity.org/website/resources/publications/2011/2011-12-15-editorial-engineering-H5N1>

⁴ Laurie Garrett. Flu Season. *Foreign Policy*. January 5, 2012: http://www.foreignpolicy.com/articles/2012/01/05/flu_season

⁵ Biological Weapons Convention Signatories and States-Parties: <http://www.armscontrol.org/factsheets/bwcsig>

⁶ Katherine Harmon. What Really Happened in Malta This September When Contagious Bird Flu Was First Announced. *Scientific American*. December 30 2011: <http://blogs.scientificamerican.com/observations/2011/12/30/what-really-happened-in-malta-this-september-when-contagious-bird-flu-was-first-announced/>

⁷ Peter Palese and Taia T. Wang. H5N1 influenza viruses: Facts, not fear. *Proceedings of the National Academy of Sciences of the United States of America*. Published online before print January 25, 2012: <http://www.pnas.org/content/early/2012/01/24/1121297109.full.pdf+html>

⁸ Michael J Selgelid. Governance of dual-use research: an ethical dilemma. *Bull World Health Organ* 2009;87:720-723: <http://www.who.int/bulletin/volumes/87/9/08-051383.pdf>

A recent article in the [Canadian Press](#)⁹ reports that a “small – in relative terms – group of technical experts will be invited to Geneva in mid-February to begin the difficult task of trying to break an impasse arising from the proposed publication of controversial bird flu research... Participants will include representatives of the Dutch and American research teams that conducted the studies, experts from WHO’s network of influenza laboratories and people with first-hand involvement in the dispute.”

The *Canadian Press* article quotes Dr Keiji Fukuda, the WHO’s assistant director-general for health security and environment, who says: “We are not setting this up as a political meeting. We are setting this up as a meeting of extremely knowledgeable technical people.”

Government sponsored lethal virus development *is* an important political and ethical issue for the world’s citizens. I for one am not comforted by this proposed meeting being confined to “extremely knowledgeable technical people” with possible conflicts of interest. In this regard, I refer you to the following articles (*please see full reference details in the footnotes*):

- [The handling of the H1N1 pandemic: more transparency needed](#)¹⁰
- [WHO and the pandemic flu “conspiracies”](#)¹¹
- [WHO and the pandemic flu “conspiracies” – Recent Rapid Responses](#)¹²
- [Flu experts rebut conflict claims](#)¹³
- [WHO failing in duty of transparency](#)¹⁴
- [The Swine Flu Panic of 2009](#)¹⁵
- [‘A Whole Industry is Waiting For A Pandemic’](#)¹⁶
- [In Holland, the Public Face of Flu Takes a Hit](#)¹⁷
- [Mexican flu: a bad and expensive joke](#)¹⁸

I also suggest a press release published by the industry-funded European Scientific Working Group on Influenza (ESWI), titled [Doubting the benefits of influenza vaccines is dangerous from both a scientific and ethical point of view](#)¹⁹ (26 October 2011), should be subjected to critical analysis. Ab Osterhaus, the ESWI chairman, is a contact on this press release.

This brazen attempt to stifle any questioning of flu vaccination is shocking, and must be considered along with other material which does question the benefits of influenza vaccines, such as the Cochrane Reviews [Vaccines for preventing influenza in healthy adults](#)²⁰; and

⁹ Meeting to address bird flu research impasse: WHO. The Canadian Press. Saturday Jan. 21, 2012:

<http://www.ctv.ca/CTVNews/Health/20120121/who-bird-flu-research-meeting-120121/>

¹⁰ The handling of the H1N1 pandemic: more transparency needed. Parliamentary Assembly Assemblée parlementaire.

Report: Social Health and Family Affairs Committee. Rapporteur: Mr Paul Flynn, United Kingdom, SOC:

http://assembly.coe.int/CommitteeDocs/2010/20100604_H1n1pandemic_E.pdf

¹¹ Deborah Cohen and Phillip Carter. WHO and the pandemic flu “conspiracies”. British Medical Journal. 12 June 2010.

Volume 340, 1274-1279: <http://www.bmj.com/content/340/bmj.c3257?tab=full>

¹² WHO and the pandemic flu “conspiracies” – Recent Rapid Responses. BMJ 2010;340:c2912:

<http://www.bmj.com/content/340/bmj.c2912?tab=responses>

¹³ Declan Butler. Flu experts rebut conflict claims. Nature. Published online 8 June 2010 | Nature 465, 672-673 (2010):

<http://www.nature.com/news/2010/100608/full/465672a.html>

¹⁴ WHO failing in duty of transparency. Leading Edge. The Lancet. Vol 10, August 2010, 505:

<http://download.thelancet.com/pdfs/journals/laninf/PIIS147330991070147X.pdf>

¹⁵ Philip Bethge et al. The Swine Flu Panic of 2009. Spiegel Online 03/12/2010:

<http://www.spiegel.de/international/world/0,1518,682613,00.html>

¹⁶ Johann Grolle and Veronika Hackenbroch. Interview with Epidemiologist Tom Jefferson – ‘A Whole Industry Is Waiting

For A Pandemic’. Spiegel Online 07/21/2009: <http://www.spiegel.de/international/world/0,1518,637119,00.html>

¹⁷ Enserink, Martin. In Holland, the Public Face of Flu Takes a Hit. Science. 16 October 2009. Vol 326, 350-351.

¹⁸ Ekkelenkamp, Miquel. Mexican flu: a bad and expensive joke. Nrc.nl>archieff. 12/05/2009:

http://vorige.nrc.nl/article2239027_ece

¹⁹ Doubting the benefits of influenza vaccines is dangerous from both a scientific and ethical point of view. European Scientists Fighting Influenza. Press message: 26 October 2011:

http://www.eswi.org/userfiles/files/ESWI_press%20release.pdf

²⁰ Jefferson T, Di Pietrantonj C, Rivetti A, Bawazeer GA, Al-Ansary LA, Ferroni E. Vaccines for preventing influenza in healthy adults. The Cochrane Library. Published Online: 7 JUL 2010. Assessed as up-to-date: 2 JUN 2010:

<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001269.pub4/abstract>

[Vaccines for preventing influenza in the elderly](#)²¹; and the systematic review and meta-analysis published in the Lancet, i.e. [Efficacy and effectiveness of influenza vaccines](#)²². A paper on which Dr Osterhaus and Dr Fouchier are included as authors should also be included in the mix, i.e. [Annual vaccination against influenza hampers development of virus-specific CD8+ T cell immunity in children](#)²³.

The WHO has indicated we are experiencing a [vaccine boom](#).²⁴ In 2009, Linda Johnson, [Associated Press](#), advised: "Vaccines now are viewed as a crucial path to growth, as drug companies look for ways to offset a slowing of prescription-medicine sales amid intensifying generic competition and government pressure to restrain prices under the federal health-care overhaul".²⁵ In a report in [New Scientist](#) in September 2011, Debora MacKenzie says: "While the rest of the pharmaceutical sector struggles to keep afloat as expiring patents send profits plummeting, the vaccine industry has become remarkably buoyant."²⁶

A recent press release on PR Newswire (January 2012) titled [Influenza Vaccine Market Opportunities and Challenges: Worldwide Forecast](#) notes: the "last few years have seen renewed interest in the vaccines market, overcoming the prevailing view that vaccines are a low-margin business with high barriers to entry. The flu vaccines market has been at the forefront of this trend, partially fuelled by the fear of an impending pandemic. As a result global influenza vaccine market has experienced phenomenal growth in recent years at a compound annual growth rate of more than 65% between 2008 and 2010. This growth was mainly driven by the global spread of H1N1 influenza. But in the year 2011 H1N1 pandemic flu vaccine market declined due to waning threat of swine flu disease. However seasonal influenza vaccine market is predicted to grow year on year and cross US\$ 4 Billion by 2015."²⁷

Obviously there is big money in flu vaccines...

It is time for a broad investigation of the ever-expanding 'influenza industry', including scrutiny of relationships between vaccine manufacturers and governments and other public bodies. (Consideration of the [doubts around Tamiflu](#)²⁸ also needs to be included in this investigation.)

This is particularly pressing in light of the ongoing calls for [compulsory vaccination](#) of medical staff²⁹, and continuing [pressure on the general population](#) to be vaccinated with flu vaccines of questionable benefit.³⁰

²¹ Jefferson T, Di Pietrantonj C, Al-Ansary LA, Ferroni E, Thorning S, Thomas RE. Vaccines for preventing influenza in the elderly. The Cochrane Library. Published Online: 17 FEB 2010. Assessed as up-to-date: 6 OCT 2009:

<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004876.pub3/abstract>

²² Osterholm MT, Kelley NS, Sommer A, Belongiz EA. Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis. The Lancet Infectious Diseases. Vol. 12 No. 1 pp 36-44:

<http://minnesota.publicradio.org/features/2011/10/documents/flu.pdf>

²³ Bodewes R et al. Annual Vaccination against Influenza Virus Hampers Development of Virus-Specific CD8+ T Cell Immunity in Children. Journal of Virology. 2011 Nov;85(22):11995-2000. Epub 2011 Aug 31:

<http://www.asm.org/asm/images/Communications/tips/2011/1111flu.pdf>

²⁴ WHO, UNICEF, World Bank, State of the world's vaccines and immunization, 3rd ed. Geneva, World Health Organization, 2009: http://whqlibdoc.who.int/publications/2009/9789241563864_eng.pdf

²⁵ Linda A Johnson. Vaccines become drugmakers' profit boosters. Associated Press. Published in The Columbus Dispatch 30 November 2009:

http://www.dispatch.com/content/stories/business/2009/11/30/vaccine_revolution.ART_ART_11-30-09_A10_7NFQQE7.html

²⁶ Debora MacKenzie. Vaccines enjoy a healthy return. New Scientist. 28 September 2011. Magazine issue 2831:

<http://www.newscientist.com/article/dn20877-vaccines-enjoy-a-healthy-return.html>

²⁷ Influenza Vaccine Market Opportunities and Challenges: Worldwide Forecast. PR Newswire. January 10 2012:

<http://www.marketwatch.com/story/influenza-vaccine-market-opportunities-and-challenges-worldwide-forecast-2012-01-10>

²⁸ Jefferson T, Doshi P, Cohen D. Effects of Tamiflu still uncertain, warn experts, as Roche continues to withhold key trial data. British Medical Journal. Tuesday, January 17. 2012: <http://www.bmj.com/press-releases/2012/01/17/effects-tamiflu-still-uncertain-warn-experts-roche-continues-withhold-key->

²⁹ Sam Davidson. New rule to make flu shots mandatory for doctors. Influenza 121doc.co.uk. January 31 2012:

<http://www.121doc.co.uk/news/doctors-to-get-flu-shots-7407.html>

³⁰ See for example: National rollout as swine flu vaccine approved. The Age. 18 September 2009:

<http://www.theage.com.au/national/national-rollout-as-swine-flu-vaccine-approved-20090918-fuyz.html> and 'Yuk' factor:

In his paper [Corruption in the Government Hospitals](#)³¹ Professor Anwar Ul Haque of the Pakistan Institute of Medical Sciences provides an interesting perspective on flu vaccination in developing countries:

...the health budget in the “3rd” world countries is very small. Even most part of this lean budget is stolen away! For example useless and unwarranted vaccines like Swine Flu vaccines are sold to suck the budget intended for the poor patients.(6-30) The corrupt elements use the power and stature of World Health Organization (WHO) and armaments of sophisticated media to create panic to fool Governments and public into buying these vaccines on the expense of treatments for far more common diseases such as malaria, anemia, tuberculosis and malnourishment etc. Some manufacturer of Swine Flu vaccines had become the WHO “experts” and promoted the sale of the vaccines from the platform of WHO. In order to sale these unwarranted vaccines on mass level and thus earning billions of] Euros they even changed the basic definition of pandemic.(27-31)

In the conclusion to his paper on corruption in government hospitals, Professor Ul Haque says:

For brin[g]ing health change the doctors and other educated people of the society have to play their active role. Freedom of expression, honest and fair evaluation and strict continuing accountability must be put in place.

Dr Keim, what steps are the NSABB taking to ensure there is appropriate political and ethical representation at the meeting to discuss bird flu research, and an objective and transparent recording of the proceedings?

In the interests of transparency, I request the matters raised in this letter be addressed in the NSABB’s forthcoming statement, which you have previously indicated will be published in *Nature* and *Science* this week.

In particular, I suggest it is imperative to clarify the United States’ position on lethal virus development in relation to its obligations under the [Biological Weapons Convention](#).

Dr Keim, I would appreciate your early response to the questions raised above. I also request your advice on the progress of your discussions with Professor Palese and his colleagues regarding publication of their letter to the NSABB.

Yours sincerely

Elizabeth Hart

***Note: I have initiated discussion on this topic, from a layperson’s perspective, on the [Bad Science Forum](#) under the title [Lethal flu virus research....](#)
<http://www.badscience.net/forum/viewtopic.php?f=3&t=27118>***

flying snot promotes flu jabs. ABC News. 6 April 2009: <http://www.abc.net.au/news/2009-04-06/yuk-factor-flying-snot-promotes-flu-jabs/1642906>

³¹ Anwar Ul Haque. Corruption in the Government Hospitals. International Journal of Pathology; 2010; 8(2): 73-81: <http://www.jpathology.com/Issues/IJP%20Vol%208-2/Corruption%20in%20the%20governemnt%20hospital-Review%20Artical.8.2.pdf>