REQUEST FOR THE COMMISSION TO STUDY
THE ETHICAL ISSUES RAISED BY
H5N1 INFLUENZA VIRUS
GAIN-OF-FUNCTION RESEARCH

Dear Dr. Gutmann,

We write on behalf of the Foundation for Vaccine Research and ourselves as scientists to request that The Presidential Commission for the Study of Bioethical Issues consider the ethical issues raised by H5N1 gain-of-function research, especially experiments to increase the transmissibility of H5N1 viruses so they can be transmitted between humans as easily as the seasonal flu.

As you know, among potential pandemic pathogens, highly pathogenic H5N1 avian influenza viruses with the possible ability to transmit from human to human are in a class of their own, with a mortality rate of nearly 60% in natural infections, according to the World Health Organization. There is no pre-existing immunity in the general population to H5N1 infection, and no vaccine. The accidental release of an artificial, laboratory-generated, human-transmissible H5N1 virus into the community has the potential to cause a global pandemic of epic proportions that would dwarf the 1918 Spanish flu pandemic that killed over 50 million people.

The Foundation shares the concerns of many institutions and individuals in the United States and overseas about the fundamental wisdom and safety of this research. The Foundation has canvassed a cross-section of life scientists and finds that a majority considers the creation in the laboratory of a pathogen more lethal than exists in nature is morally and ethically wrong. Indeed, a majority are of the opinion that there is no scientific justification that outweighs the moral and ethical problems.

The Foundation also shares the concern of many institutions that civil society has not been consulted on this issue. Remarkably, there has been little discussion about the morality and ethics of such research.

In March 2012, the Foundation took the lead in organizing a 2-day international symposium, “H5N1 Research: Biosafety, Biosecurity and Bioethics,” that was held on April 3 and 4 at the Royal Society in London. Organized in partnership with the Royal Society and the UK Academy of Medical Sciences, the symposium was made possible by grants from the Bill & Melinda Gates Foundation, the American Society for Microbiology (ASM), the Fondation Mérieux, the German National Academy of Sciences – Leopoldina, Institut Pasteur, and the UK/Eire Society for General Microbiology (SGM), all of whom sent representatives to the meeting. The symposium was the first and remains the largest meeting convened to date on the H5N1 issue. It was also the first international meeting open to the public and the first webcast live: http://royalsociety.org/events/2012/viruses/
The presentations on the ethics of H5N1 gain-of-function research at the Royal Society symposium and the spirited discussions that followed gave participants an idea of the deep complexity of the ethical issues and highlighted the need for high-level expert input on the issue.

In the last six months, there has been little or no discussion of the ethical issues in subsequent meetings or in print. In the few cases when bioethics were touched on, the bioethicists were voices on the margins of a primarily scientific discussion. Indeed, the settings for subsequent meetings precluded a larger ethical debate about whether the benefits of this research warranted the risks, or whether the research, considering the ethical and moral problems, should have been conducted in the first place. The result is that ethics have been given short shrift.

The H5N1 studies represent the first of no doubt many such studies involving other potential pandemic pathogens. Gain-of-function studies with the H5N1 virus are being conducted in China, and a team in The Netherlands is expanding their H5N1 studies to include studies with the H7N7 virus, and has announced plans to conduct similar gain-of-function studies with the SARS coronavirus. Just ten days ago we learned that a team in Germany has conducted experiments to see what it would take for canine distemper virus to be transmitted from dogs to humans.

The expansion of this kind of work and the proliferation of labs that will inevitably follow is of grave concern in the absence of any overarching guidance on the ethics of this type of work. The ethical issues arising from work designed to create pathogens more dangerous than exist in nature, with the potential for global transmission, go beyond the more familiar ethical issues arising from dual-use research: the creation of human-transmissible H5N1 viruses subjects uninformed, non-consenting persons to a novel risk, which may (in many of our views, does) exceed the potential benefits of pursuing the research. Whatever one’s views on the merits of the research, this is all taking place in the context of weak governance and no ethical guidance documents.

A study of the ethical and moral issues raised by H5N1 gain-of-function research undertaken by the Commission would provide valuable intellect and energy on an issue of global importance. Such a study would inform and contribute to the international discussion that has been called for by the NSABB and the WHO, and endorsed by U.S. government. Addressing the ethical issues in a compelling way would mark an important advance in the continuing debate.

Since most gain-of-function studies to date have been funded by the United States, and in view of the passions ignited by the H5N1 controversy worldwide, the Foundation considers that it is not only appropriate but also necessary for the Presidential Commission for the Study of Bioethical Issues to undertake a study of the ethical issues raised by H5N1 gain-of-function research. In the present context, it is important and preferable that an independent U.S.-based expert bioethics panel should study the ethical issues (as opposed to the WHO or the European Commission).

Attached are some background materials that may be of interest: A World View published in today’s issue of Nature, a letter from the Foundation to the CDC in response to their request for comment, an opinion piece in the Financial Times, and two papers in Science and mBio by Lipsitch et al.
We look forward to hearing whether the Commission will consider undertaking a study of the ethical issues raised by H5N1 gain-of-function research.

Sincerely,

[Signature]

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(Attachments)