

Wider attention for GOF science

In October 2014, the U.S. government paused funding for so-called gain-of-function (GOF) research involving pathogens with pandemic potential, to allow for a systematic assessment of its benefits and risks. The topic raises critical questions for society as a whole, and decisions cannot be left with the scientific community alone.

The current suspension in funding is the latest twist in unsteady policy-making regarding GOF research that is designed to enhance the transmissibility or pathogenicity of disease-causing agents. The issue came to public notice in 2012 over the question of whether to publish experiments that showed it was possible to develop variants of the H5N1 avian influenza virus that would transmit readily in a mammal. Scientists engaged in this research adopted a voluntary suspension of studies so that there could be more discussion and public education, and later lifted the self-imposed moratorium. The U.S. National Science Advisory Board for Biosecurity (NSABB), charged with reviewing such matters, initially voted to publish redacted versions of the work, but after meetings in which the science and implications of the information were clarified, relented in a split vote. After several unrelated incidents of mishandling of dangerous pathogens in federal laboratories came to light in 2014, the U.S. government paused funding for GOF research on coronaviruses that cause severe acute respiratory syndrome (SARS) and Middle Eastern respiratory syndrome (MERS), as well as influenza virus.

Proponents of GOF research argue that it may aid in recognizing emerging pandemic strains and help identify optimal vaccine strains. Proponents of caution raise questions about whether the research will be conducted safely and the potential for discoveries to be intentionally misused. The NSABB now has the lead in conducting a process of assessment and advice over the next 12 months, which will take advantage of input from workshops organized by the U.S. National Academies* and will include an independent evaluation of benefits and risks.

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The task ahead is complex and difficult. Important but subtle scientific distinctions have to be made, as evidenced by the lifting of the latest moratorium (2 months after it was instituted) for MERS viruses, which have no laboratory animal model and cellular receptors that vary markedly across species. A particular challenge in conducting a risk/benefit analysis is considering the combination of very low-probability events and potentially catastrophic consequences. Intelligent policy will need to be explicit, defining precisely under what circumstances and conditions distinct types of research in specified locations should go forward. Policy will need to take into account the perspectives and concerns of both biosecurity and biosafety.

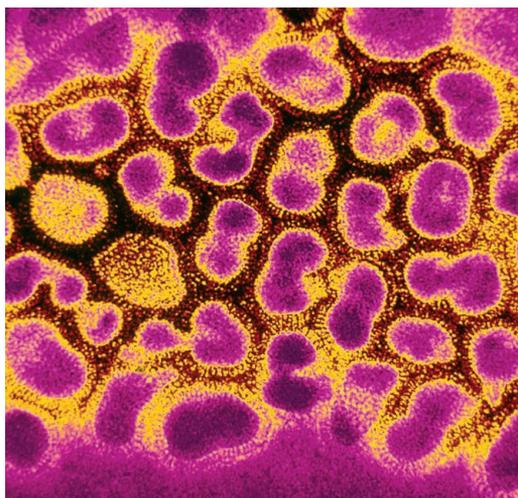
Implications for attracting scientists to or discouraging them from crucial fields of investigation are a genuine concern. From a global perspective, policies and practices will need to be harmonized across countries if the world is to maintain a strategic and coherent approach. The World Health Organization is a logical (if problematic) place to seek

such coherence in international policy and practice.

Even a comprehensive and well-informed risk/benefit analysis will not itself lead to clear-cut answers. Judgments by those from different scientific and lay perspectives will be critical to sound decision-making. The input of scientists and funders is no longer sufficient to make appropriate, socially defensible choices about research that has such social dimensions. This is different from corporate judgments or governments deciding what is in their national interests. The benefits and risks of doing such research do not apply equally to all people, institutions, or countries, and a rigorous risk/benefit analysis will have to be mindful of these inequities and hear from various stakeholders.

How scientists participate in the deliberations, as engaged listeners even more than as expert instructors, can serve to reinforce public confidence in science, well beyond the specific types of studies that are in question.

— Harvey V. Fineberg



“...decisions cannot be left with the scientific community alone.”



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