



Certain studies on the MERS coronavirus (yellow) are being halted for a review.

BIOSECURITY

U.S. halts two dozen risky virus studies

One-year “pause” to develop new policy on controversial research that enhances pathogens

By Jocelyn Kaiser

Ebola isn't the only virus scaring the U.S. government. It is also worrying about a hypothetical threat: a deadly virus created in a lab. On 17 October, in an unprecedented step, federal officials moved to stop so-called gain-of-function (GOF) studies on three kinds of viruses. To buy time for experts to work out a government-wide policy for weighing the risks and benefits of such work, officials are halting all new funding for the studies and are asking researchers doing ongoing work to agree to a voluntary moratorium.

Although the microbiology community had expected some sort of “pause” for weeks, the move took some researchers by surprise because it potentially covers studies on any influenza strain—not just two bird strains that are already tightly restricted—as well as two coronaviruses: SARS, which panicked Asia in 2003, and MERS, now spreading from camels to people in the Middle East. The funding pause affects about two dozen projects supported by the National Institutes of Health (NIH), but the voluntary moratorium could put the brakes on more. As *Science* went to press, researchers were scrambling to consult with their program officers at NIH to find out whether they would have to halt their work.

The debate kicked off 3 years ago when two separate research teams revealed that they had altered the H5N1 avian influenza strain, which doesn't normally transmit among mammals, so that it could spread between ferrets. Many scientists worried that if the new lab strains were accidentally or deliberately released, they could spark a deadly pandemic. But proponents argued that such studies will help public

health researchers detect an impending flu pandemic and prepare vaccines.

After researchers agreed to a 1-year voluntary moratorium on GOF H5N1 studies and the U.S. government issued new rules, the work resumed last year. But concerns have reignited as new papers on risky human-made flu strains have come out in recent months. Meanwhile, reports of mishandled samples at the U.S. Centers for Disease Control and Prevention have raised questions about safety at U.S. high-containment labs. Scientists known as the Cambridge Working Group collected nearly 300 signatures on a July statement calling for studies on “potential pandemic pathogens” to be “curtailed” until the risks and benefits could be evaluated; another large group, Scientists for Science, defended the studies as safe but also called for a meeting to discuss the issues (*Science*, 5 September, p. 1112).

The funding pause, developed by the White House Office of Science and Technology Policy and the Department of Health and Human Services, applies to new studies “that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.” The government also “encourages” those now doing this work, even if not with federal funding, to stop. Testing of naturally occurring forms of these pathogens can continue as long as the tests don't increase risks.

During the pause, U.S. officials plan to evaluate the risks and benefits of GOF experiments and to develop a policy for approving new studies. The process was scheduled to begin this week with a meeting of the National Science Advisory Board for Biosecurity (NSABB), an ad-

visory group that has not convened for 2 years. The National Academies' National Research Council and Institute of Medicine will also hold a workshop to discuss the scientific issues; they will later review NSABB's recommendations, which are due within 6 months. The plan is to have a final policy in place within a year, when the pause will end—except, presumably, for studies that don't pass the new risk assessment process.

Two researchers who led the original H5N1 studies—Yoshihiro Kawaoka of the University of Wisconsin, Madison, and Ron Fouchier of Erasmus MC in the Netherlands—said they are ready to comply.

Coronavirus researcher Stanley Perlman of the University of Iowa in Iowa City said his lab's efforts to generate a new MERS strain will have to stop for now. His goal is to develop a virus that sickens mice, making possible a mouse model for testing MERS drugs and vaccines. Adapting a virus to mice usually makes it less pathogenic in humans, he notes. He's hoping to qualify for an exception in the policy for studies “urgently necessary to protect the public health.” Says Perlman: “I think it [the policy] caught a fish that wasn't meant to be caught.”

Despite the confusion over exactly which studies will be affected, those who think GOF studies need more scrutiny are celebrating. Harvard University epidemiologist Marc Lipsitch, who co-organized the Cambridge Working Group, says he is “very pleased.” Boston University microbiologist Paul Duprex, a leader of Scientists for Science, says that although he is “not a fan of blanket bans,” there is “precedent” because of the earlier voluntary moratorium. He looks forward to “the presentation of hard evidence.” The debate will continue before NSABB this week, where both Lipsitch and Duprex are expected to speak. ■

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