The Hon Mark Butler MP
Minister for Health and Aged Care

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Senator Marielle Smith
Chair
Community Affairs Legislation Committee
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Dear Chair Marielle

Thank you for your correspondence of 7 December 2022 requesting advice on what further information, if any, can be provided about the 17 identified research projects from the Gain-of-Function Research Review, without identifying the researchers involved.

I appreciate your advice that the Community Affairs Legislation Committee is mindful that it does not contribute to any threats to individuals and that the Committee does not dispute the grounds on which I have made a claim of public interest immunity in respect to the question on notice asked by Senator Matt Canavan during the 2022–23 Budget Estimates hearing of the committee on 10 November 2022.

With respect to the provision of further information about the '17 identified reports', I would like to emphasise that the National Health and Medical Research Council (NHMRC) has already reported information about the relevant research in its review report, which is available at www.nhmrc.gov.au/about-us/news-centre/gain-function-research-review. The provision of any further information beyond what has already been published in this report risks identifying the researchers involved.

As explained in Section 5.2 of the review report, information about the 17 identified gain-of-function research projects is presented in general terms and, where appropriate, aggregated form. The report does not identify individual researchers or non-Government institutions associated with relevant gain-of-function research. This approach was necessary to protect researchers from serious threats to their personal and professional lives, as has been experienced by scientists around the world in the context of research on COVID-19.

The information in this section of the report includes the types of research, the anticipated benefits and outcomes from the research, and confirmation that all controls as required under Australia's regulatory framework were in place during the conduct of any research.

The types of research are reported as follows:

- 13 projects involved virological studies (Cedar virus, Ebola virus, filovirus, flavivirus, Hendra virus, influenza viruses including influenza A, lyssa viruses, Marburg virus, Nipah virus, rabies virus, SARS-like coronavirus, West Nile virus)
- four projects involved bacteriological studies (Escherichia coli, Mycobacterium ulcerans, Streptococcus pyogenes, Yersinia pestis)

- 13 projects involved the use of live animals (mouse, ferret), while some other projects involved the use of animal tissue/cell lines (e.g. bat tissue, avian cells) and three projects involved the use of human tissues
- four projects did not involve the use of either an animal model or human tissues.
- 13 projects involved the use of genetically modified organisms (GMOs) in Australia and one project involved the use of GMOs in other countries (Canada, USA).

The report also provides information about the anticipated benefits of the 17 research projects identified by the review, which is based on the research proposals (e.g. grant applications or detailed project plans) and notes that, in some cases, the intended research was not conducted or completed. The anticipated benefits are reported as follows:

- forecasting and preparing for a 'bad' flu season, and potentially developing new drugs that inhibit severe flu, by identifying the features of influenza viruses that predict virulence
- determining the vulnerability of a species (including birds and humans) to 'bird flu' outbreaks by advancing understanding of the natural evolution of an avian influenza virus from a low pathogenic virus to a highly pathogenic variant
- improving the ability to detect swine-origin influenza strains of concern (to pigs and to humans) by identifying the molecular and genetic basis for pathogenicity of swine-origin influenza
- enabling the rapid identification and response to flaviviruses in Australia (flaviviruses are mosquito-borne viruses that can cause large disease outbreaks, such as Dengue virus, West Nile virus, yellow fever virus and Japanese encephalitis virus) by advancing understanding about the viral factors that determine the transmission and virulence of flaviviruses
- determining vaccine protection against lyssaviruses (including the Australian bat lyssavirus (flying fox variant) that can be transmitted from bats to humans, causing serious illness) by creating a laboratory animal model (mouse) to study lyssaviruses more readily
- potentially developing vaccines and therapeutics to filoviruses and henipaviruses (for example, Cedar virus, Ebola virus, Hendra virus, Marburg virus and Nipah virus) by identifying the viral factors that determine the virulence and pathogenicity of these viruses
- assessing the potential threat of bat viruses to human health by investigating the mechanisms of cross-species transmission of potential zoonotic viruses carried by bats (noting that this research originally proposed to investigate the potential threat of SARS-like coronavirus, which is found in bats and is genetically closely related to the virus that caused the 2003 SARS outbreak in humans, but the research ended up focusing on, and identifying, other viruses (not coronaviruses) that had not previously been identified in bats)
- advancing understanding of how pandemics happen by determining the origin and evolution of a bacterial pathogen involved in an historical pandemic, including understanding the mutations that contributed to its increased virulence
- enabling the detection of disease-causing bacteria and the development of better treatments and vaccines by identifying how various bacteria make toxins, cause disease and develop resistance to antibiotics.

Of the 17 research projects identified, all were conducted at appropriate research sites such as universities or CSIRO research sites. As part of the review process, further information on each project was obtained from the institution responsible for the project, which provided evidence that all controls as required under Australia's regulatory framework for the type of research involved were in place during the conduct of the research. There were no incidents involving infectious agents or GMOs reported for any of the identified projects.

The Office of the Gene Technology Regulatory (OGTR) also independently confirmed that appropriate licences were in place for each project, where such licences were required, and relevant facilities were appropriately certified. The OGTR was also satisfied that there were no significant or unresolved issues as the result of monitoring or re-certification inspections.

So, as stated in the report, while gain-of-function research may create an infectious agent that could cause harm to humans – such as a virus or bacterium that is more transmissible, virulent or pathogenic – this research was carried out because it is vitally important to prepare for, detect, treat and where possible prevent serious outbreaks of disease in humans.

Thank you for writing on this matter.

Yours sincerely

Mark Butler

9 /12/2022

cc: The Hon Ed Husic MP, Minister for Industry and Science