DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

June 22, 2022

The Honorable Joni K. Ernst
United States Senate
Washington, DC 20510

Dear Senator Ernst:

Thank you for your letter of June 2, 2022, regarding the use of dogs in research funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). NIAID is committed to funding innovative basic research as well as the development of vaccines, diagnostics, therapeutics, and other interventions for a wide variety of infectious and immunological diseases.

In fiscal year 2021, NIAID awarded a $1.8 million Small Business Innovation Research contract to Inimmune Corporation (contract #75N93021C00044) to develop a novel intranasal treatment for allergic rhinitis, which is also known as hay fever. Allergic rhinitis is estimated to affect approximately 60 million people in the U.S., and many patients do not achieve adequate relief with available medications, resulting in substantial social and economic burdens.

Although the contract to Inimmune Corporation proposed the use of murine and canine preclinical animal models, after consultation with the U.S. Food and Drug Administration (FDA), the company elected to proceed using two rodent models only. No experiments utilizing the canine model are being conducted under this contract.

Although no experiments using the canine model will be conducted under this contract, I would like to respond to questions 2 through 5 from your letter:

2. **Will any funding be provided from private sources and what percentage of the funds for these experiences will be provided by NIAID?**
   No private sources will provide funds for the research conducted under this contract to Inimmune Corporation.

3. **Will any funding for these tests be provided to labs in China?**
   No funding will be provided to China or China-based investigators or research institutions through this contract.

4. **What would the cost be to taxpayers if a non-animal testing model was used?**
   FDA requires testing in animal models to demonstrate preclinical safety and efficacy to move a candidate toward clinical testing with the eventual goal of licensure. In this case, Inimmune Corporation will use rodent models.

5. **The FDA has stated dog testing is not mandated for human drugs. Did NIAID consult with the FDA to specifically discuss whether dog testing was required? Did NIAID propose the use of any alternatives to dog or other animal testing?**
The sponsor of a potential clinical candidate is responsible for consulting with FDA. Since Inimmune Corporation, not NIAID, is the sponsor in this case, it was the company's responsibility to consult with FDA. As noted above, the company did consult with FDA and ultimately decided not to proceed with utilizing the canine model.

   The initial contract proposal, including the description of use of the animal models, was rigorously evaluated by an independent panel of experts. All research projects submitted to NIH are carefully evaluated during peer review to determine if an alternative method could effectively be used in place of animals, and if the applicants have appropriately determined and justified the number of animals required to conduct the research. NIH has established guidance, procedures, and protocols to ensure that intramural and extramural scientists maintain the highest possible standards for the humane care and use of animals in research, including efforts to explore alternatives to the use of animal models.

I want to assure you that NIH and NIAID take the welfare of animals in research very seriously. Research conducted or supported by NIH that involves the use of research animal models is governed by the Public Health Service Policy on Humane Care and Use of Laboratory Animals (the PHS Policy).[1] The PHS Policy is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (U.S. Principles).[2] Compliance with the PHS Policy is a collaborative effort between the NIH, scientific investigators, and research institutions. The administration and coordination of the PHS Policy with regards to NIH-funded animal research is carried out by the NIH Office of Laboratory Animal Welfare (OLAW). NIH OLAW provides specific guidance, instruction, and materials to institutions that must comply with the PHS Policy. One of NIH OLAW's primary functions is to advise NIH Institutes and Centers and awardee institutions concerning the implementation of the PHS Policy.

Thank you for your interested in NIAID's research program. I hope this information is helpful. Best regards.

Sincerely,

Anthony S. Fauci, M.D
Director
National Institute of Allergy
and Infectious Diseases

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[1] PHS Policy on Humane Care and Use of Laboratory Animals. https://olaw.nih.gov/policies-laws/phs-policy.htm
[2] U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. https://olaw.nih.gov/policies-laws/gov-principles.htm