

May 14, 2009

Ronald Schultz, Ph.D.  
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Dear Dr. Schultz,

For more than a year, PETA has communicated with the Rabies Challenge Fund (RCF) in order to (1) determine whether RCF had attempted to receive a waiver from the USDA to conduct a parallel serologic study; (2) ensure that RCF is submitting serological data to the USDA so that tests such as these could be avoided completely in the future; (3) clarify the conditions in which the 80 beagles in the study are being kept; and (4) ensure that the unvaccinated dogs who will be exposed to the rabies virus will have access to around-the-clock veterinary care and immediate euthanasia as soon as their painful symptoms begin.

After a review of our communications with RCF, we must conclude that RCF has not made proper efforts to conduct the challenge tests for canine rabies vaccination humanely and has misrepresented its intentions to its donors. As a result, it would appear that donors are funding a protocol that will result in the death of 80 dogs without even the intention of conducting parallel studies that could ultimately replace such lethal tests.

In a September 25, 2008 letter, Jean Poster, V.M.D, Ph.D., provided additional insights that have not been acknowledged, including the clinical reality that RCF will be unable to secure humane euthanasia of dogs purposefully exposed to rabies. RCF's refusal to seek USDA approval for a humane protocol before this study began has assured difficulty in making further procedural amendments, which RCF has stated as its intention. Furthermore, RCF has failed to explain to its donors that even a successful outcome of the challenge study, while essential to the confirmation of longer periods of immunity, requires the death of every dog involved in the study, half of whom will die after being intentionally infected with the rabies virus without benefit of the vaccine.

In two letters written over the course of six months, your position on the goals of the RCF-sponsored rabies vaccine studies has reversed. In your correspondence from October 1, 2008, you mention that your laboratory "will conduct serologic 'antibody' studies ... with the aim of demonstrating a correlation between protection from challenge with one or more of the different rabies antibody tests." This approach would provide information necessary to validate the use of available serologic methods, replacing the challenge method that requires the confinement and killing of, in the case of the current study, 80 beagles. Your most recent letter from April 16 of this year reverses this intention, saying instead that serologic tests are "not something that USDA could or



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would accept as a replacement for future challenge studies with rabies vaccines.” This change of direction is startling not only in its contrast with your previously stated intentions, but also in its insistence that scientifically-merited variances cannot be granted in vaccine studies. As a result, RCF apparently no longer intends to collect information in this study that is vitally necessary to replacing vaccine tests that continue to be responsible for the painful deaths of a large number of dogs.

### What happened?

#### RCF in July 2008

“Ron Schultz has undertaken informal dialog with USDA senior officials, in his capacity as advisor to the vaccine industry and regulatory body. He has decades of experience in the field and attends meetings with these folks regularly. At this point, we have not made progress in changing their views, BUT, he and I [W. Jean Dodds, DVM, RCF Co-Trustee] together are planning to present a more formal proposal to them. **We have 4 + years to accomplish what we view as an important need to change the regulations as currently written for endpoint challenge testing -- before anything involving challenge of these healthy dogs [vaccinates and controls] with rabies virus has to take place according to the current regulatory protocol.**”

#### RCF in October 2008

“[W]e will conduct serologic (antibody) studies as part of the “duration of rabies vaccine immunity” project with the aim of demonstrating a correlation between protection from challenge with one or more of the different rabies antibody tests.”

#### RCF in April 2009

**“...USDA is not likely to change their requirements, especially when rabies vaccines are involved ...** At the end of the 5 year study period, when the dogs will be challenged with live rabies virus, none of these infected dogs will be allowed to live. All infected (challenged) dogs, vaccinated and control, will be humanely euthanized at the end of the challenge period.”

#### RCF in April 2009

“There is no written proposal from the RCF to USDA about a parallel titer study, because this is not something that USDA would or could accept as a replacement for future challenge studies with rabies vaccines.”

PETA members have many concerns about the continued use of tests that routinely end in the intentional infection of dogs with the rabies virus, leading to painful early symptoms that include ataxia, anorexia, convulsions, seizures, encephalitis and paralysis. This study, which has already begun, has no clear requirements for the provision of even the

most basic needs of the confined beagles. We are extremely concerned that initial plans to include parallel serologic testing have apparently been abandoned without explanation.

RCF has the benefit of your long-standing relationship with USDA and once again we urge you to submit serological data to the USDA and work with the agency to initiate their consideration of serological models as an appropriate correlate of the challenge test, so that some progress can be made from this study in moving toward titer testing in place of booster vaccinations for rabies. In this way, the RCF and others may be able to avoid future horrific studies such as the one you are currently conducting. I hope you will let me know that you will do so.

Sincerely,

A handwritten signature in black ink, appearing to read "Samantha Dozier". The signature is fluid and cursive, with the first name "Samantha" being larger and more prominent than the last name "Dozier".

Samantha Dozier, Ph.D.  
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