

Dr Richard E. Hill, Director  
USDA Aphis Center for Veterinary Biologics  
510 South 17<sup>th</sup> St Suite 104  
Ames, IA 500100

June 16, 2014

Dear Dr. Hill:

I read with great interest the statement you made concerning the Veterinary Services 2015 Initiative:

Dr. Richard Hill, Director for the Center of Veterinary Biologics

“Veterinary Services 2015 Initiative - the purpose is to make a Stronger VS for the 21st Century. As the recognized animal health leader, VS is committed to the well-being of animals, people and the environment. VS integrates One Health Principles with their business objectives along with their infrastructure to effectively collaborate with local, state, tribal, national and international partners.”

The key words you stated Dr. Hill are your “committed to the well-being of animals, people”. There is an issue with veterinary vaccines for dogs that has resulted in the death of a magnitude of pets, suffering by many more, loss of companionship prematurely by their owners and the emotional suffering that the pet owners endured. I am speaking about the false assumption cited by the American Animal Hospital Association (AAHA) that K9 vaccines stimulate an immune system so all size dogs get the same 1cc volume whether a 2 pound Chihuahua or a 160 lb Great Dane. This false assumption has caused the unnecessary death of many small dogs. Here I will present clear evidence of scientific studies that support my assertion and an expert immunologist who concurs. In addition I will present evidence of a veterinary research institution that doses its vaccine based on weight, not the immune system. This is also true with many human vaccines as well.

I have read the letter titled CENTER FOR VETERINARY BIOLOGICS DRAFT NOTICE NO. 327 dated August 9, 2010 in which you state, “Studies should be conducted to support revaccination intervals on labels of products containing fractions that lack historical data to support annual revaccination recommendations.” We need to also draft a notice that says, “Studies should be conducted on lowering the vaccine volume as the weight of the dog decreases for products that lack historical data to support the recommended one ml volume for all size dogs both giant and toy breeds.”

I am not sure you realize this Dr. Hill but there are a large and growing number of veterinarians who lower their rabies vaccine volume administered to small breed dogs and puppies. The veterinarians don't want to hurt their patients in the process of vaccination. This is against United States Federal and State Statutes which state the veterinarian must follow the manufacturer recommendation of 1cc for all size dogs. Clinically these veterinarians have observed disproportionate numbers of anaphylaxis and other adverse reactions occurring in small dogs when given a full one cc volume of rabies. Now we have several scientific studies that support their clinical assessment and protocol adjustment. These veterinarians are no longer willing to expose small dogs to unneeded risk and over-vaccinate by giving a full cc volume. Veterinarians have been placed in a compromised position of either obeying the law and disobeying their Hippocratic Oath or obeying their Hippocratic Oath (part of their Aesculapian Authority as doctors) and breaking the “law”. Here are a few of the studies supporting our position that one cc volume is an overdose for the smaller dogs.

First look at the study titled, "Adverse events diagnosed within three days of vaccine administration in dogs" (The Purdue Study of 2005) (1). This was a study of 1.2 million dogs which showed that Vaccine Associated Adverse events (VAAE) decreased significantly as body weight increased. Or another words the smaller the dog the risk of reaction goes up significantly! Why? Because the one cc volume is over-stimulating the immune system as the weight of the dog decreases. Let's look at a second study titled, "Effects of body weight on antibody titers against canine parvovirus type 2, canine distemper virus, and canine adenovirus type 1 in vaccinated domestic dogs" (2). In this study the authors conclusion in the final paragraph states, "Unlike cows, pigs and cats, body weight differs markedly among dog breeds, so the existing method of administering the same vaccine dose for all dogs regardless of body weight, may need to be reconsidered. The data obtained from the present study indicating antibody titers against CPV-2 and CDV are low for large dogs and high for small dogs should therefore prove useful in compiling future vaccination protocols". A third scientific study titled, "Factors influencing the antibody response of dogs vaccinated against rabies, 2007"(3) showed antibody titers increased as body weight declined for both of the commercial inactive rabies vaccines tested. A fourth study titled, "Factors associated with the success of rabies vaccination of dogs in Sweden"(4), stated, 'The probability of success of rabies vaccination depends on the type of vaccine used, number of rabies vaccinations, THE BREED SIZE OF THE DOG, age at vaccination and number of days after vaccination when the antibody titers are tested. The need for a booster vaccination regimen is recommended for LARGER BREEDS OF DOG.' Another words the larger the dog the lower the immune response to the same volume of rabies vaccine.

Combine this information with the JAVMA article titled, "Post marketing surveillance of rabies vaccines for dogs to evaluate safety and efficacy"(5) and it becomes clear that studies to evaluate volume reduction based on the weight of the dog are long overdue. This report showed that "nearly 10,000 adverse event reports (all animal species) were received by manufacturers of rabies vaccines.....Approximately 65% of the manufacturer's reports involved dogs. This report also states "Rabies vaccines are the most common group of biological products identified in the adverse event reports received by the CVB (Center for Veterinary Biologics). Veterinarians are not required by law to report adverse reactions to vaccines, to which the World Small Animal Veterinary Association stated in their 2007 Vaccine Guidelines that there is: "gross under-reporting of vaccine associated adverse events which impedes knowledge of the ongoing safety of these products," and in an article entitled, "A New Approach to Reporting Medication and Device Adverse Effects and Product Problems, (JAMA – June 2, 1993. Vol.269, No. 21 p.2785) Dr. David Kessler, former head of the Food & Drug Administration, reported that "only about 1% of serious events are reported to the FDA."

"In light of the 10,000 adverse reactions to the rabies vaccine in the JAVMA report, 65% of which were in dogs, the estimated 1% reporting of "serious" events by the former head of the FDA means that the actual number of dogs that had adverse reactions to the rabies vaccine would be more like 650,000"(6) with 36,000 immediate deaths!!!! Based on the 2005 Purdue Study most of these deaths would be small breed dogs. Now you can see why it's imperative we force the vaccine manufactures to do the studies that will prove the volume of rabies vaccine administered to dogs can be lowered as the weight of the dogs decreases (dose dependent on weight) while maintaining the vaccines effectiveness in protecting the dog and their owners from rabies . Once proven the vaccine inserts must include dosing instructions based on weight.

Look at the vaccine dosage schedule for primates at the University at California Davis Primate Center. (7)

5.1.3 Administer the tetanus vaccine via subcutaneous injection.

Table 1: Tetanus Dosage

Weight (kg)	Dosage (ml)
1.0 – 2.5	.05
2.5 -5.0	0.1
5.0 – 10.0	0.2
>10.0	0.3

Clearly the veterinary researchers at the UC Davis Primate Center believe vaccines are dose dependent on weight, it does not matter what species.

Dr. Juan Lafaille, an immunologist at New York University, states, “I agree that body weight should be a consideration when deciding the amount of antigen or vaccine to be administered, and I am surprised that it wasn't a factor..... The dose of antigen becomes crucial to diminish the impact of an anaphylactic reaction, certainly a high dose per body weight would lead to death much more than a low dose of the same antigen and this would be proportional to the weight of the animal.”

Ronald Hines DVM PhD gives a comprehensive look at this issue with a 17 page article “Is One Vaccine Dose Size really right for all dogs?” <http://www.2ndchance.info/onesize4all.htm> (8)

In private practice it is common for new dog owners of small breed dogs to be given handouts by their breeder bring to their veterinarians advising them to lower the volume of all vaccines for these smaller dogs.

In conclusion the time is overdue for the CVB under the USDA to initiate studies that would prove vaccines are dose dependent on weight. Far too many small breed dogs have already died needlessly. In a time where all 50 states now have made it a felony charge for animal cruelty and pets are “more and more being recognized not as property but as living beings with a right to be protected, the USDA must keep with the times and take this letter seriously. Dr. Hill you stated that the CVB is committed to the well being of animals and people. Immediate action must be taken to assert your authority in requiring the necessary research be done with expedience. This is a tragedy of great proportions involving the unwarranted and unnecessary loss of life. Please show commitment to these animals and people by taking the necessary steps to get this research underway. I believe strongly in vaccination and specifically rabies vaccination. However I do not believe in needlessly over-vaccinating smaller dogs, resulting in death and suffering. Protect the Pets is a worldwide movement and organization that speaks for the innocent. We must protect the innocent, we must Protect the Pets.

Sincerely and God Bless,

John M. Robb DVM  
[www.protectthepets.com](http://www.protectthepets.com)  
[drrobb@protectthepets.com](mailto:drrobb@protectthepets.com)  
203-731-4251

- 1.) Adverse events diagnosed within three days of vaccine administration in dogs – George E. Moore, DVM, MS, PhD, DACVPM; Lynn F. Guptill, DVM, PhD, DACVIM; Michael P. Ward, BVCS, MS, MPVM, PhD; Nita W. Glickman, MPH, PhD; Karen K. Faunt, DVM, DACVIM; Hugh B. Lewis, BVMS, DACVP; Lawrence T. Glickman, VMB, DrPH
- 2.) Effects of body weight on antibody titers against canine parvovirus type 2, canine distemper virus, and canine adenovirus type 1 in vaccinated domestic adult dogs – Masayuki Tafuchi, Kazuhiko Namikawa, Takuya Maruo, Miyoko Saito, Janathan Lynch, Hiroeki Sahara
- 3.) Factors influencing the antibody response of dogs vaccinated against rabies – Lorna J. Kennedy, Mark Lunt, Annette Barnes, Lorraine McElhinney, Anthony R Fooks, David N. Baxter, William E. R. Ollier
- 4.) Factors associated with the success of rabies vaccination in Sweden – Louise T Berndtsson, Ann-Kristin J Nyman, Esteban Rivera, and Berndt Klingeborn
- 5.) Postmarketing surveillance of rabies vaccines for dogs to evaluate safety and efficacy – Timothy S. Frana, DVM, MPH, PhD, DACVM; Nancy E. Clough, DVM, PhD, DACVM; Donna M Gagewood, DVM, MS; Charles E. Rupprecht, VMD, PhD
- 6.) 2008 Rabies Vaccine- JAVMA Report Adverse Reactions In Dogs – Kris L. Christine
- 7.) University of California at Davis Primate Research Center Manual 5.0 Procedure – 5.1 Tetanus Immunizations
- 8.) Is One Vaccine Dose Size Right For All Dogs – Ron Hines, DVM, PhD