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White Paper**

## **Vaccine Liability Issues for Veterinarians**

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**Authors:**

**Sarah Babcock DVM, JD**

*Washington, D.C.*

**Doug Jack, Solicitor**

*Ontario, Canada*

**Charlotte Lacroix DVM, JD**

*Whitehouse Station, N.J.*

**Christine Pfeiffer JD**

*Flint, MI*

**John Thomas JD**

*Washington, D.C.*

**Editor:**

**Elizabeth Settles, DVM, JD, DACVIM**

*Blaine, WA*

Over the last 50 years, the development of effective vaccines for the control of many serious infectious diseases of dogs and cats has been one of the major success stories of veterinary medicine. Vaccination continues to be the only safe, reliable, and effective way of protecting animals against major infectious diseases. Vaccination is also the most cost-effective method of controlling these diseases. The purpose of this white paper is to evaluate the current legal issues concerning vaccination.

There are two major factors that determine the use of vaccines: safety and efficacy. When deciding to vaccinate a particular animal be sure that the risk of vaccination does not exceed the risk associated with the chance of contracting the disease itself. The other consideration is efficacy. Vaccines are not always effective. In diseases such as foot and mouth in pigs, immunity response is transient and relatively ineffective. Based on these considerations, some researchers have recommended that animal vaccines be divided into categories based on their importance. The first category is essential or core vaccines-these vaccines are required to protect against common, dangerous diseases and a failure to use them would place an animal at significant risk of disease or death. The second category is optional or non-core vaccines. These are directed against diseases for which the risks associated with not vaccinating may be low. Risks from these diseases are determined by the location or lifestyle of an animal. When vaccines are used to control disease in a population of animals rather than in individuals, the concept of herd immunity becomes important. This means that the resistance of an entire group of animals to a disease is a result of the presence within that group of a proportion of immune animals. Herd immunity reduces the probability of a susceptible animal meeting an infected one so that the spread of disease is slowed or terminated. In this model it is acceptable to lose individual animals from disease while preventing epizootics. This model is rarely used in companion animal medicine.<sup>1</sup>

Most vaccines require an initial series in which protective immunity is initiated, followed by re-vaccination at intervals to ensure that protective immunity remains at an adequate level. Because maternal antibodies passively protect newborn animals, it is not usually possible to successfully vaccinate animals very early in life. Since it is impossible to predict the exact time of loss of maternal immunity, the initial vaccination series will generally require administration of at least two and possibly more doses. Vaccines are provided in the standard dose, and this dose should not be divided to account for an animal's size. Doses are not formulated to account for body weight or age. There must be a sufficient amount of an antigen to trigger the cells of the immune system and provoke an immune response. This amount is not related to body size. The timing of vaccinations has now become a major point of contention in the veterinary profession.<sup>2</sup>

### **The Science of Vaccines: Efficacy**

During the last few years our understanding of immune response after vaccination has completely changed. These changes are based on a more detailed knowledge of the complexity of the immune system. The immune system is broadly comprised of two parts: innate and adaptive. The innate immune defenses are characterized by rapid

assimilation and less specific responses, which are of limited duration. These include humoral factors like complement and certain cytokines and cellular components such as natural killer cells, granulocytes, macrophages and dendritic cells. The adaptive immune defenses include antigen specific immune responses which need more time to develop, are more specific and last longer. The adaptive immune system needs to interact with the innate immune system for effective activation especially with antigen presenting cells including monocytes, macrophages and most importantly dendritic cells.<sup>2</sup>

The cascade of activation of the immune system starts with early “danger” signals which are necessary for an effective stimulation of the innate immune system and ends with the memory function of the adaptive immune system. All parts of the immune system work together like a network. “Danger” signals produce an effect of local tissue damage often resulting in local inflammatory responses. These responses are associated with an increased permeability of the endothelium, up-regulation of leukocytes, adhesion molecules on the endothelial cells of blood vessels and extravasation of the recruited leukocytes into the site of injury. The last step is principally triggered by chemokines, and this inflammatory reaction is the first step of the interaction between the innate and adaptive parts of the immune system.<sup>3</sup>

One important bridge between the innate and adaptive immune systems is represented by the dendritic cells of the skin. These cells are the most important antigen presenting cells in the body. They migrate to the site of inflammation and take up pathogens or cell debris. After uptake, the material is processed and transported by dendritic cells to the lymphoid tissues for antigen presentation. This dendritic cell migration is combined with a maturation and differentiation of the immature dendritic cells into mature dendritic cells. The maturation leads to an up regulation of the expression of molecules encoded in the major histocompatibility complex and cellular adhesion molecules responsible for the interaction with other cells, and co-stimulatory molecules involved in the activation of cells of the adaptive immune system. Up regulation of activation molecules as well as cytokine receptors and chemokine receptors are also part of this maturation process.<sup>3</sup>

Following this maturation, dendritic cells are able to interact, in the lymph nodes, with the second branch of the adaptive immune system: antigen specific T lymphocytes. T lymphocytes consist of T Helper cells and Cytolytic T cells. Only distinct major histocompatibility molecules are able to present foreign antigens to their respective cells. Two signals are required for activation of T cells. The first activation signal is a signal for antigen specificity generated by the interaction between major histocompatibility receptors and T-cell receptors. This second signal is based on an interaction between T-cell receptors and antigen presenting cells such as dendritic cells. Without the second signal, T cells become inactivated and develop anergy and tolerance to the respective antigens.<sup>2,3</sup>

Activation of T lymphocytes is combined with clonal expansion and differentiation to the respective effectors cells. Cytolytic T cells develop their cytolytic activity against, for example, virus infected cells. Helper T cells show a differentiation

into two sub-types of Helper cells. One group provides more help to the cellular immune response and is characterized by an enhanced interferon gamma production. The second type is more engaged in B-cell help and in support of the humoral antigen specific response. These are characterized by the production of Interleukin 4, TGF-beta and Interleukin 10. The aim of effective vaccination is the generation of memory cells; these include both memory B and memory T cells which are then responsible for a fast and efficient immune response during a secondary contact with specific antigens.<sup>2,3</sup>

The focus for monitoring vaccine specific immune reactions has principally been on the humoral branch of the adaptive immune system. While other parts of the immune response are equally if not more important in the response to viral infection, measuring antibodies is the preferred laboratory method of assessing immunity as the techniques are simple in comparison to measuring cell mediated immunity and can be performed on an easily collected and stable sample. Perhaps the most extensive evaluation of the serologic response to routine vaccination has been serological response for the United Kingdom and Scandinavian pet travel schemes. A rabies antibody test is a required part of the procedure, and the results of this test together with the vaccination history and timing of sampling have provided insight into the response of cats and dogs to routine vaccination. The results of this testing showed significant variation in the response of individual cats and dogs to rabies vaccination. Overall 4-5% of animals had less than the required antibody threshold, and a small portion of animals had no detectable antibodies by repeated vaccination. In another study canine distemper virus and canine parvovirus antibody titers were performed in healthy dogs brought to a veterinary hospital for re-vaccination. One hundred twenty-two dogs with previous vaccinations were surveyed. Of these dogs 27% had less than protective canine parvovirus titers and 21% of dogs had less than protective canine distemper virus titers. Although this study was limited geographically, it does serve to remind us that not all animals will react the same to a given vaccination protocol.<sup>4,5</sup>

Studies have been performed which show that serum titers for antibodies against canine distemper virus, canine adenovirus-1 and canine parvovirus correlate with protection.<sup>6,7,8</sup> The protective role of serum antibodies against canine parainfluenza virus is less clear-cut. Tizard and Ni at the request of the AVMA Council on Biologic and Therapeutic Agents reviewed the use of serologic testing to assess immune status in companion animals. They found that, in general, detection of an antibody titer in serum from an animal indicates that the animal has encountered the agent and an immune response has developed. Although we know that the immune system is more complex than just the humoral arm, high antibody concentrations in the extracellular environment will serve to inhibit the spread of viruses between cells and, thus, promote host resistance. Serologic tests measure the current status of an animal and cannot predict future protective status with accuracy.<sup>9</sup> This is an especially important when assessing relative risk and amount of challenge exposure. The immune system has a finite protective ability. Whether it can protect an animal will depend, in part, on the amount of challenge exposure by an infectious agent. Managers of poultry and swine operations have embraced widespread use of a panel of ELISA tests to determine whether their animals are susceptible to infection and require vaccination. For companion animal

practitioners conditions are different, although the basic principle is the same. Given the success of routine serologic testing for determining protection in the swine and poultry industries, it is reasonable to assume the same techniques could be applied to companion animals.

Although the definitive test of immunity in veterinary medicine is viral challenge, such challenge studies by necessity are performed on experimental dogs under tightly controlled conditions and do not reflect the field situation. For example in one such study 40 specific pathogen free puppies, 6 to 8 weeks of age that were seronegative to the antigen fractions in a test vaccine were randomly allocated to two groups: vaccinated and unvaccinated (control). The puppies were separated and housed in complete isolation and observed daily following vaccination and challenge for a total period of 3 years. A subgroup of puppies was challenged with a distemper vaccine that was intracranially administered. Another subset was challenged with canine parvovirus administered by intranasal and oral routes. A third group was administered canine adenovirus-1 intravenously. While the routes of administration of the distemper and canine adenovirus certainly did not reflect a field situation that a veterinary practitioner would encounter, it should also be considered that the volume of infecting viral particles was probably much higher than would be encountered in a natural environment. Challenge infections, for example using canine parvovirus, would typically employ 100,000 tissue culture infectious doses/ml.<sup>9</sup>

In human medicine challenge studies are obviously not the gold standard. More precise analysis of the immune response after vaccination can be done using assays which use antigen specific proliferation and T-cell products correlating with T-cell activation. Detailed knowledge about the immune system of carnivores is limited and therefore not many alternatives for detection of correlates of protection exist. In carnivores the existing tools enable only a limited view on the cellular antigens specific immune response after vaccination. In the future, hopefully, veterinary medicine will also be able to take advantage of these laboratory tools.

### **The Science of Vaccines: Safety**

Adverse reactions to the administration of vaccine to companion animals have been recognized since the advent of modern vaccinology. A range of clinical or procedural adverse reactions is now well documented, but available data suggest that the prevalence of such reactions is extremely low relative to the number of vaccines administered. Vaccination should be considered a safe and essential procedure for the control of infectious disease in the individual or population. Traditional post marketing surveillance of veterinary vaccines relies on veterinarians and owners to voluntarily submit reports of suspected reactions to manufacturers or the USDA. A study in 2005 using a large electronic medical database calculated the incidence rates and potential risk factors for vaccine associated adverse events within three days of administration of vaccine to dogs. There were 4678 adverse events (38.2/10,000 dogs vaccinated) associated with the administration of 3,439,576 doses of vaccine to 1,226,159 dogs. The adverse event rate decreased significantly as body weight increased.<sup>10</sup> Some studies have

reported breed specific increases in hypersensitivity reactions, for example in dachshunds. Factors known to cause vaccine reactions include the primary vaccine agent or antigen, adjuvants, preservatives, stabilizers, and residues from tissue cultures used in vaccine production.

A study in the United Kingdom initiated by the National Office for Animal Health, addressed the question of whether there was an increased prevalence of ill health in dogs in the three-month period following vaccination. The study was performed by questionnaire to pet owners registered at 28 veterinary practices. A total of 3966 usable questionnaires were obtained from 9055 issued. The main finding of the survey was that 16.4% of dogs vaccinated within the previous three months had an episode of illness in a two-week period preceding completion of the questionnaire, whereas 18.8% of dogs that received vaccine more than three months previously had an episode of illness within the same two weeks. This suggests that vaccination does not increase the prevalence of illness within the immediate three-month post-vaccination period.<sup>11</sup>

### **What are Negligence & the Standard of Care for Vaccines?**

Our courts and juries decide negligence on a case by case basis in light of the specific facts and circumstances of each situation, but, veterinarians should be aware of a few general principles. First and foremost, it is important to note that a veterinarian can be found negligent even if he or she did not intend to cause harm. Simply put, "I didn't mean to" is no defense to "you should have known better". A simple mistake can lead to liability.

Secondly, veterinarians can be found negligent even if the rest of their colleagues would have acted in the exact same way. Judges can determine that the entire industry is at fault if it is in the public's interest. Judge Leonard Hand, a famous judge once wrote in his opinion "[c]ourts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission."<sup>12</sup> Hence it is a false security to rely on what the rest of your colleagues are doing.

In the United States "...conformity to custom is not in itself an exercise of care as a matter of law" (30 AmJur2nd Evidence §1123). In the past, by adhering to label instructions, vets could shift liability to the vaccine manufacturer. But in 1996, the US Supreme Court refused review of the *Lynbrook Farms vs. SmithKline Beecham Corp.* (117 S.Ct.178) case, declaring that only USDA requirements of safety, efficacy, potency and purity must be met by the manufacturer. If the vaccine meets these requirements any harm that it may cause must stay with the veterinarian, even if the label instructions were followed.

To recover damages from a veterinarian based on negligence, a client must prove four elements by a preponderance of the evidence, meaning it is more likely than not that the veterinarian erred:

Duty of Care. Clients must show that their veterinarians "owed" them a duty of care to provide veterinary services of a certain standard. This element is easy to prove, because courts almost always find that once a veterinarian has agreed to provide veterinary services, the veterinarian also has assumed the legal duty to take reasonable care in providing such services

Breach of Standard of Care. A duty to provide services within the standard of care is breached when veterinarians fail to meet the standard of care as established by the veterinary profession, that is, when they fail to act with the level of skill and learning commonly possessed by members of the profession in good standing. It is at this stage that expert witnesses are hired to testify as to what is the standard in the case at issue.

Proximate Cause. Clients must then prove that the veterinarian's failure to provide services within the standard of care "proximately" or "closely" caused the harm suffered by the clients. If the harm suffered by the client is not a result of the veterinarian's actions or omissions, it would be unfair to hold the veterinarian responsible.

Damages. Even after they have proved negligence, clients also must establish that they suffered harm resulting from such negligence. Since animals are considered as property under the law and most state courts do not recognize loss of companionship, this harm is usually in the form of an economic loss. As a result veterinary malpractice awards are usually much lower than in human malpractice cases and clients usually only recover the fair market value of the animal, costs incurred for veterinary care, and loss of income or profits in cases where the use of the animal is lost. However, we are seeing more and more states entertain the possibility of awarding non-economic damages and this is likely to increase the scrutiny with which standards of care are evaluated as well as the number of lawsuits filed against veterinarians.

### **What about Informed Consent?**

The legal doctrine of informed consent requires medical practitioners to obtain a patient's consent prior to performing a medical procedure by first discussing with the patient of the risks and benefits of, and alternatives to the procedure. The underlying rationale of the doctrine is that the patient should have the opportunity to make an informed decision by having the necessary facts before consenting to have the procedure done.

The informed consent doctrine traditionally applied to physicians, but has been extended to other health care practitioners, including veterinarians, as well. Courts looking at informed consent in veterinarian-client/patient cases generally use case law and legal standards from traditional human medicine<sup>13</sup> where informed consent issues usually arise in medical malpractice cases.

Over the past half-century, two competing standards of what constitutes disclosure sufficient to comply with informed consent requirements have emerged – first,

the “reasonable practitioner” (or “professional”) standard, and more recently, the “reasonable patient” standard, with the states being about evenly split regarding which standard they have adopted.<sup>14</sup>

The reasonable practitioner standard, as its name suggests, is practitioner-based, analyzing a practitioner’s duty to disclose based on what a reasonable practitioner would disclose under similar circumstances.<sup>15</sup> This standard for disclosure must be established by expert testimony.

Under the reasonable patient standard, disclosure is patient-oriented. That is, the practitioner must disclose all information that “would be regarded as significant by a reasonable person in the patient’s position when deciding to accept or reject a recommended medical procedure.”<sup>16</sup>

Liability for failing to provide informed consent usually arises in the context of medical malpractice/professional negligence causes of action. To establish liability against a veterinarian under such a claim, the plaintiff must show: (1) the basis for the duty owed to the plaintiff (such as the acceptance by a veterinarian to provide services to a pet owner), (2) breach of the applicable standard of care by the veterinarian, and (3) that the veterinarian’s breach of the standard of care was the proximate cause of the animal’s injury.<sup>17</sup> Additionally, an aggrieved plaintiff may have a cause of action for battery based on a veterinarian’s failure to obtain informed consent, breach of an express warranty or contract, or fraud and/or misrepresentation (based on a guarantee or representation by the veterinarian of a certain result that does not occur), and some jurisdictions recognize the tort of “lack of informed consent” against physicians.

To establish the tort of lack of informed consent, the Ohio Supreme Court has held that the following elements must be met: (1) the physician must fail to disclose material information to the patient (including risks and dangers inherent and/or potentially involved in the proposed treatment); (2) the undisclosed risks or dangers actually materialize and are the proximate cause of harm to the patient; and (3) a reasonable person in the position of the patient, informed of the risks and dangers, would have decided not to undergo the treatment.<sup>18</sup>

Notably, in an unpublished opinion, the Court of Appeals of Ohio, in a case against a veterinarian involving informed consent, observed that although no Ohio court has recognized the tort of lack of informed consent against a veterinarian, the acceptance of such a cause of action against veterinarians is not precluded in Ohio.<sup>19</sup> However, the Court did not decide upon this issue, as it was not before the Court in this case. Thus, it is possible that those jurisdictions that recognize the tort of lack of informed consent (separate from a cause of action for medical malpractice/professional negligence) could extend this cause of action to veterinarians.

In terms of companion animal vaccines and informed consent, guidelines have been issued by various professional organizations, including the American Animal Hospital Association (AAHA), the American Association of Feline Practitioners (AAFP),

and the American Veterinary Medical Association (AVMA), which, at a minimum, recommend that veterinarians discuss decisions about vaccinations (including risk assessment and alternate options) with the client-owner, and document such discussions in the animal's medical record.

The 2006 AAHA Canine Vaccine Guidelines recommend that any decision related to the vaccination of a client-owned pet should only be made after a discussion with the client, and that such discussion must be fully documented in the animal's medical record. The 2006 AAFP Feline Vaccine Advisory Panel Report also recommends that veterinarians obtain and document obtainment of a client's informed consent to treatment (including vaccinations), and that veterinarians use caution in statements they make to clients regarding the safety and effectiveness of vaccines.

Also, the AVMA Executive Board approved a policy regarding informed consent ("owner consent") in May 2007 which was then revised in November 2007 which provides in pertinent part that veterinarians "...in a manner that would be understood by a reasonable person, veterinarians should inform animal owners or their authorized agents of the diagnostic and treatment options available. They should also provide an assessment of the risks and benefits of such choices, a prognosis ... and that "[t]he owners or authorized agents should indicate that their questions have been answered to their satisfaction, the information received by them has been understood, and that they are consenting to the recommended treatments or procedures."

In addition to these guidelines, a particular state Veterinary Medical Board may also have guidance regarding vaccinations and informed consent. For example, the Texas Board of Veterinary Medical Examiners issued a "Board Statement of Policy on Vaccination Protocols and Informed Consent" ("Board Statement") in November 2005.<sup>20</sup> In the Board Statement, the Texas Board noted that "[i]ndicators are that not enough is being done to inform the client of the need for the offered vaccines and the securing of informed consent." Further, the Board Statement provided that veterinarians obtain informed consent related to vaccine administration by: (1) discussing the "risks versus benefits of vaccination on a pet-by-pet basis", (2) providing options to the vaccine (including less frequent vaccination if this provides the necessary protection), and (3) obtaining the client's consent for the recommended vaccination in a written "authorization to vaccinate" (if a written vaccine consent form is not used, then the veterinarian should document enough information in the patient's record to show that the veterinarian acquired the client's approval for the vaccines after being informed of its benefits and risks and the client should initial such medical record entry).

### **What about Statutory Authority for Vaccines?**

Today, we often think only of the Food and Drug Administration (FDA) when the subject of the regulation and use of animal health products arises, but historically, to the extent that there was a federal responsibility, this fell to the U.S. Department of Agriculture (USDA). The first federal food and drug act, enacted in 1906 (P.L. 59-384, 21 U.S.C. §§ 1-15, repealed in 1938 by 21 U.S.C. § 392(a)) put this responsibility in

USDA, and it made no distinction between products for humans and other animals. Congress enacted the first U.S. statute for the regulation of veterinary vaccines and other biological products with the Virus-Serum-Toxin Act of 1913, 21 USC §§ 151 et seq. (hereafter the VST Act). The statute contained no distinction between the roles of veterinarians and laymen. The VST Act remained unchanged until amendments were enacted in 1985 to bring the statute in to the second half of the Twentieth Century. Throughout its history, the authority to carry out the VST Act has been under the jurisdiction of the U.S. Secretary of Agriculture, who has delegated the authority to various agencies within the department at various times. The authority now resides with the Animal and Plant Health Inspection Service (APHIS).

When FDA was established in the 1940s, the authority for enforcing the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq., hereafter the FDC Act) was transferred from USDA to FDA in a predecessor to the Department of Health and Human Services. Except, however, Congress left meat inspection and veterinary biologics with USDA. See § 902 of the FDC Act (21 U.S.C. § 392).

Regardless of where the authority lay, until relatively recently, the federal agencies regulating animal health products have taken the position that they do not regulate the practice of veterinary medicine. Until the 1970s, there were very few cases or regulatory initiatives by the agencies targeting veterinarians. In that decade, however, the scientific community became concerned about the effects of residues of animal drugs in the human food supply. Toxicologists were quantifying the effects of low doses of these chemicals, and, equally importantly, test methods made it possible to find minute levels of residues in meat, milk, and eggs.

The biggest change came in the early 1980s when FDA concluded that some illegal drug residues in human foods were resulting from the use of products pursuant to veterinarians' prescriptions, and the agency published its now-famous Extra-Label Use Policy. The specifics of the policy have changed only slightly over the past 25 years, and the underlying principles continue to govern FDA enforcement policy.

Veterinarians have more leeway to prepare and distribute animal health products under the VST Act than they have under the FDC Act. The original 1913 VST statute contained a narrow definition of the types of products USDA could regulate, reflecting the prevailing political philosophy regarding the role of the federal government at the time. Local activities were not subject to USDA authority. Neither Congress nor the federal courts were interested in using their imaginations to conjure up ways that Doc Jones's treatment of a herd of pigs in western Iowa could be a federal matter. Veterinary medicine is as "local" as any profession, and USDA never attempted to exert any authority over veterinary practice. Likewise, veterinarians were left alone to produce biological products to use in their practices.

The 1985 amendments to the VST Act (P.L. 99-198 (December 23, 1985)) brought about a dramatic change in the role of the federal government. The amendments extended USDA jurisdiction to all veterinary biological products in the United States.

The USDA jurisdiction now covers even products produced and used solely within one state, and it covers products which are exempt from licensing. The Act applies to biological products prepared in a noncommercial setting, as well. The statute covers pets as well as livestock and poultry, but it does not seem to apply to products for wildlife. The statute provides, in part:

§ 151. It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange . . . in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States . . . or any place under the jurisdiction of the United States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals. . . .

21 U.S.C. § 151.

The statute now covers “any” veterinary biological product handled by “any” person “any” place in the country. And USDA is given broad authority to enforce this sweeping policy:

§ 154. The Secretary of Agriculture is authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin or analogous product for use in the treatment of domestic animals, or otherwise to carry out this chapter.

21 U.S.C. § 154.

USDA is granted the authority to make “such rules and regulations as may be necessary.” For longer than any of us can remember, veterinarians have been skilled in the “art” of producing vaccines, toxins, antiserums, etc., for treatment of a client’s herd or flock. If the product worked well, the veterinarian might use it in a neighbor’s herd, as well. Does § 154 mean that USDA regulates these activities of practicing veterinarians now?

Of course, the answer to that question is, yes, but Congress blunted the impact. At the urging of the AVMA and other representatives of the veterinary profession, Congress included in the 1985 amendments an exemption from the licensure requirements for veterinary biologics produced by animal owners and by veterinarians. It is important to note that the statutory exemption is from the licensure requirement – it is not an exemption from the prohibition on preparation, distribution or use of any worthless, contaminated, dangerous, or harmful product. Quoting the statute again:

§ 154a. . . . The Secretary shall exempt by regulation from the requirement of preparation pursuant to an unsuspended and unrevoked license any virus, serum, toxin, or analogous product prepared by any person, firm, or corporation –

(1) solely for administration to animals of such person, firm, or corporation;

(2) solely for administration to animals under a veterinarian-client-patient relationship in the course of State licensed professional practice of veterinary medicine by such person, firm, or corporation;

21 U.S.C. § 154a.

Thus, Congress gives USDA jurisdiction of all veterinary biological products produced in the United States, but it allows veterinarians to prepare biologics for their clients' animals without seeking licenses for the products. Likewise, an animal owner does not need a license to prepare products for use in his or her own animals.

APHIS promulgated regulations to implement the statutory exemption and to define the "veterinarian-client-patient relationship." This is now found at 9 CFR § 107.1, which reads, in part:

**§ 107.1 Veterinary practitioners and animal owners.**

Products prepared as provided in paragraphs (a) and (b) of this section and establishments in which such products are prepared, shall be exempt from preparation pursuant to unsuspended and unrevoked establishment and product licenses. . . . The shipment or delivery for shipment anywhere in or from the United States of any exempted product which is worthless, contaminated, dangerous, or harmful is prohibited, and any person shipping such product, or delivering such product for shipment, shall be subject to the sanctions under the Act.

(a)(1) Products prepared by a veterinary practitioner (veterinarian) solely for administration to animals in the course of a State licensed professional practice of veterinary medicine by such veterinarian under a veterinarian-client-patient relationship and establishments in which such products are prepared shall be exempt from licensing under the Act and regulations. Such a relationship is considered to exist when:

(i) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian; and when

(ii) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s) . . . ; and when

(iii) The practicing veterinarian is readily available for follow-up in the case of adverse reactions or failure of the regimen.

(2) Veterinarians preparing products subject to the exemption for products under this section shall maintain and make available for inspection by Animal and Plant Health Inspection Service representatives or other Federal employees designated by the Secretary such records as are necessary to establish that a valid veterinarian-client-patient relationship exists and that there is a valid basis for the exemption under this section.

#### 9 CFR § 107.1.

APHIS has from time to time conducted investigations and taken other regulatory actions against veterinarians and veterinary practice groups that have stretched the exemption. There have been no cases in this area that have produced any published court opinions. This is an issue that is likely to continue to spark activity, however; as livestock production has become more concentrated, there are more animals under the management of a single producer, and there are more animals under the care of a single veterinarian.

Historically, the veterinary profession has been regulated by state government. Not only does the state license practitioners, but state law governs the standards of practice of veterinarians, including veterinary medical malpractice, products liability, breach of contract, etc. This is not the case, however, with regard to liability for veterinary biological products.

In a span of less than 10 years, USDA's jurisdiction went from a position of keeping its hands off the so-called "intrastate" veterinary biologics industry to declaring that all veterinary biologics are governed by federal standards and any conflicting state laws are pre-empted. Beginning in the late 1980s, APHIS took regulatory initiatives to establish that it was pre-empting the field of government regulation of veterinary biological products. In a regulation to implement the general licensing provisions of the amended VST Act, APHIS stated that it was exercising its statutory authority to occupy the field of government regulation, and any state or local law imposing additional or inconsistent requirements on a veterinary biologics producer were overruled and ineffective. There have been several federal court decisions interpreting these USDA regulations, and the decisions uniformly affirm the agency's assertion of authority – and apply the principle of federal preemption to bar plaintiff-animal-owners' claims for damages allegedly arising from defective vaccines licensed by USDA. The landmark case is *Lynnbrook Farms v. SmithKline Beecham Corp.*, 79 F.3d 620 (7th Cir.), *cert. denied*, 519 U.S. 867, 136 L.Ed. 2d 118, 117 S.Ct. 178 (1996). This case and its progeny were very well summarized by the judge who wrote the opinion in, and, in the following paragraphs, I have paraphrased in part and quoted in part Judge Rudolph T. Randa's opinion in that case:

*Lynnbrook Farms* holds that APHIS regulations concerning the safety and effectiveness of animal vaccines preempt all state common law causes of action that seek to impose requirements that are different from, or in addition to, the federal standards. On the basis of the VST Act and its legislative history, the Seventh Circuit found that there was an “unquestionable congressional intent to create national, uniform standards for the preparation and sale of animal vaccines.” 79 F.3d at 625. The *Lynnbrook Farms* court thus inferred that Congress granted APHIS the power to preempt state law in furtherance of this goal, and APHIS exercised this authority through the promulgation of regulations. APHIS made its intentions perfectly clear in the preamble to final regulations implementing the new, expanded VST Act:

Where safety, efficacy, purity, and potency of biological products are concerned it is the agency’s intent to occupy the field. This includes, but is not limited to, the regulation of labeling. Under [VST Act amendments], Congress clearly intended that there be national uniformity in the regulation of these products.

...

APHIS does not agree that States should be allowed to add various restrictions . . . based upon a need to protect domestic animals or the public health, interests or safety. Any restrictions, other than those which are to address a local disease condition, should be Federally imposed so that they are uniform nationwide.

...

States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States. Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA’s authority to determine which biologics are pure, safe, potent and efficacious.

57 Fed. Reg. 38758, 38759 (August 27, 1992). See *Cooper v. United Vaccines, Inc.*, 117 F. Supp. 2d 864 (E.D. Wis. 2000) for a succinct summary of *Lynnbrook Farms* and its progeny.

There may be situations in which the plaintiff animal owner has a claim which has nothing to do with the safety or effectiveness of a vaccine. For instance, if the farmer contracted for delivery by a specified date, and delivery did not occur for a significant time thereafter, the farmer’s cause of action would not be pre-empted just because the subject of the contract was a veterinary vaccine.

There are also situations in which the animal owner alleges that the damages were caused because the vaccine producer failed to comply with the APHIS requirements. This argument was made, in fact, in *Cooper v. United Vaccines, Inc.*, but the judge held that the plaintiff offered no evidence to support this allegation. At about that time, in another case, the plaintiff persuaded a federal judge in Georgia that there was sufficient

evidence of a breach of regulatory requirements to overcome the defendant's motion for summary judgment. The case is *Gresham v. Boehringer Ingelheim Animal Health, Inc.*, 1996 U.S. Dist. LEXIS 22157, 1996 WL 751126 (N.D.Ga.), but we have no further reported opinion from that case.

All of these cases addressing federal preemption involve commercial vaccine manufacturers. All the vaccines were licensed by USDA, and USDA considered the products to be pure, safe, potent, and effective. Do the principles of pre-emption protect a veterinarian from claims under state law in the same way the vaccine manufacturer is protected? At this point, we have to speculate, because the question has not been decided in any published judicial opinions.

Does the rule in § 154a exempting products prepared by a veterinarian from licensing extend the pre-emption umbrella over the preparation or distribution of those products? The products prepared by a veterinarian pursuant to § 154a are still subject to VST Act standards, regardless of their licensing status, and the veterinarian may be subject to enforcement action for the distribution of products that are found to be worthless, contaminated, harmful, or dangerous – potentially subjecting a veterinarian to penalties consisting of either civil or criminal fines. So, is USDA “occupying this field,” as well? Good question!

### **“The Ethical Aspects of Vaccination Protocols”** **Legal Consequences for Ethical Breaches**

The prudent veterinary practitioner will acknowledge that there are potentially important ethical considerations relating to the adoption of vaccination protocols that may differ from manufacturer's recommendations and labelling. Arguably, the adherence to ethical tenets may be the more crucial in that they do not always attract a great deal of intuitive attention despite the fact that a breach of the ethical requirements can result in significant legal sanctions. What follows is a general review of some of the common ethical dilemmas that the veterinarian might face related to this topic together with a discussion of the legal consequences for ethical breaches. The reader should note that there are some variations in the legislative authorities for the ethical requirements the breach of which would give rise to allegations of professional misconduct from state to state. A careful review of the state veterinary legislation would be recommended.

In the event that a veterinary practitioner elects to adopt a protocol for vaccination and re-vaccination that differs from the manufacturer's stated recommendations in peer-reviewed publications, package inserts and labelling, beyond the other legal doctrines referred to in this paper, the veterinarian must be aware of the various ethical considerations that apply. In general terms, a breach of an ethical tenet (legislated or merely acknowledged by the profession as adopted) would be considered unprofessional conduct (or, in some states, professional misconduct) giving rise to state imposed sanctions.

### *Observing Generally Accepted Standards of Practice*

In some jurisdictions, the observance of accepted standards of practice not only is relevant to negligence standards of care issue but also is an ethical requirement. The failure to adhere to the standard of practice can be considered professional misconduct. In the context of this paper, it would be important for the practitioner to conduct adequate investigation of the common practice among like practitioners relating to the vaccination protocols. A review of the local literature, consultations with fellow practitioners and active participation in continuing education all represent the manner in which a local practitioner might determine what the standard of practice is in his or her jurisdiction.

### *Failure to Fulfill the Terms of a Client Engagement*

A client typically presents his or her animal to the veterinarian with the expectation that the vaccination protocol will be effective in avoiding the malady which the vaccine was intended to prevent. In the event that the particular protocol adopted leads to evidence that the vaccine did not perform an adequate preventive function, then arguably the practitioner has breached a moral obligation to fulfill the terms of engagement.

### *Making a Misrepresentation to the Client*

Similar to the observation above, by failing to observe the package instructions for the vaccine and asserting that a different re-vaccination cycle be adopted without scientific support and against protocols recommended by AVMA, AAFP and AAHA may result in an allegation of making a misrepresentation to a client. Such an ethical breach, founded in notions of trust, would be considered very serious by any licensing board.

### *Representations without Professional Support*

A similar ethical tenet relating to making a representation that could not be supported by professional opinion would draw similar sanctions. The prudent practitioner will ensure that his or her views on vaccination protocols is widely accepted in his or her jurisdiction.

### *Issuance of Certificates*

From time to time practitioners are requested to issue certificates confirming that an animal has been properly vaccinated against common maladies; such certificates are commonplace for international travel upon which foreign authorities will seek reliance. Serious consideration must be given prior to issuing such certificates that may, if issued under protocols unsupported by scientific research, prove to be false. The issuance of a false certificate is a serious breach of veterinary ethics.

### *Unexpected Death and Necropsy*

In some jurisdictions, it is required that a veterinarian offer an independent necropsy to a client in the event that an animal dies in unexpected circumstances. One might consider that the death of an animal caused by the failure of a vaccine due to unsupported protocols would give rise to such an obligation.

### *Unprofessional Conduct Generally/Conduct Unbecoming*

It is arguable that the adoption of protocols unsupported by scientific research and recommendations of AAHA, AAFP, and AVMA could be viewed as conduct that would be regarded by other members of the profession as dishonourable or unprofessional or conduct unbecoming a veterinary professional. Such conduct would constitute a breach of veterinary ethical tenets.

### **Legal Consequences for Ethical Breaches**

Most practitioners will be aware that the breach of any of the ethical requirements referred to above can give rise to allegations of misconduct before the state licensing board having authority to sanction the veterinarian. In the event that the practitioner were to be found guilty of professional misconduct, then certain sanctions can be imposed as follows:

#### *Reprimand*

A verbal or written reprimand admonishing the conduct of the veterinarian may be issued and, in some cases, reported to the members of the profession.

#### *Monetary Fine*

In some jurisdictions, a monetary fine may be levied.

#### *Suspension of License*

A temporary removal of the license to practice veterinary medicine may be the result of a more serious breach of veterinary ethics. Several states now require completion of certain CE courses prior to removing a veterinarian from probation or as a condition to lifting the suspension of the license.

#### *Revocation*

A permanent removal of the license to practice veterinary medicine is reserved for the most serious cases.

#### *Costs*

In some jurisdictions, the costs incurred by the state in investigating and prosecuting cases of professional misconduct may be recovered from the veterinarian found guilty of an ethical breach.

### **So How Can I Avoid Liability in My Vaccine Protocol?**

The best method to completely avoid liabilities associated with revaccination is not entirely clear. In contrast to the FDA, the USDA does not have jurisdiction to fine or otherwise penalize veterinarians from deviating from label recommendations. As discussed previously, there are several avenues that a client may pursue to “punish” a veterinarian for veterinary care that they believe is unacceptable. These include most commonly, suing for a medical malpractice claim and/ or a failure to inform of the risks and benefits of vaccination as well as reporting the veterinarian to the state board.

So what can a veterinarian actually do to protect themselves from liability? The answers are the same as they are for many other veterinary legal questions. We recommend the following:

- (1) Stay abreast of developments in the veterinary profession – these include scientific, peer-reviewed articles supporting appropriate vaccination protocols as well as following decisions in your jurisdiction by the courts as well as your state medical board.
- (2) Practice the duty to inform – this includes not only a verbal discussion with the client, but also a simple pamphlet that outlines the reasons for different vaccination intervals for individual pets, as well as a disclosure of vaccination risks, current research on duration of immunity and a position statement by your practice outlining the policy of your practice concerning vaccination.
- (3) Obtain the owner’s consent prior to vaccinating the animal.
- (4) Properly document in your medical records the rationale for pursuing a particular course of treatment – this includes taking a history of the pet’s environment and exposure to diseases preventable by vaccines, as well as a physical examination to determine the overall health of the pet.

Veterinarians have been using 3-year vaccination protocols for over 10 years, and to date, neither AVMA Professional Liability Trust nor ABD Insurance has received any malpractice claims based on veterinarians using such protocols. There is no universally accepted standard of care in the industry, a claim of negligence or malpractice could be defended regardless of the protocol used by the veterinarian. Because vaccines are under the jurisdiction of the USDA and not FDA, the veterinarian’s medical judgement trumps the label recommendation. This is the current situation, however this may change in the future. Stay abreast of scientific and legal changes through AVMA, your local and state associations and by consulting veterinary attorneys in your area.

## Footnotes:

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- <sup>5</sup> Burr P.D. & Snodgrass D.R. *Serological response to rabies vaccination for the pet travel scheme*. Res Vet Sci 72 (Suppl A), 25.
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- <sup>9</sup> Tizard I. & Ni Y. *Use of serological testing to assess immune status of companion animals*. JAVMA 213(1) July 1998.
- <sup>10</sup> Moore G.E. et al. *Adverse events diagnosed within three days of vaccine administration in dogs*. JAVMA 227 (7) October 2005.
- <sup>11</sup> Edwards D.S. et al. *Vaccination and ill-health in dogs: a lack of temporal association and evidence of equivalence*. Vaccine 22, 3270, 2004.
- <sup>12</sup> The T. J. Hooper [ 60 F. 2d 737 (2<sup>nd</sup> Cir. 1932).
- <sup>13</sup> McEachern Nunalee & G. Robert Weedon, *Modern Trends in Veterinary Malpractice: How Our Evolving Attitudes Toward Non-Human Animals Will Change Veterinary Medicine*, 10 Animal L. 125, 154 (2004).
- <sup>14</sup> Hon. Armand Arabian, *Informed Consent: From the Ambivalence of Arato to the Thunder of Thor*, 10 Issues L. & Med. 261, 263 (1994).
- <sup>15</sup> *Smith v. Weaver*, 407 N.W.2d 174, 178 (Neb. 1987).
- <sup>16</sup> *Arato v. Avedon*, 858 P.2d 598, 607 (Cal. 1993).
- <sup>17</sup> *Price v. Brown*, 680 A.2d 1149, 1152 (Pa. 1996).
- <sup>18</sup> *Nickell v. Gonzalez*, 477 N.E.2d 1145, 1148 (Ohio 1985).
- <sup>19</sup> *Lawrence v. Big Creek Veterinary Hosp.*, No. 2006-G-2737, slip op at 3-4 (Ohio App. Sept. 7, 2007).
- <sup>20</sup> Available at the Texas Board of Veterinary Medical Examiners website, [www.tbvme.stat](http://www.tbvme.stat)