

Liability Related to Vaccination

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In the United States, licensed vaccines are subject to the Virus, Serum, and Toxin Act (VSTA) of 1913 (9 CFR ?101.2(w) [1991]). Consequently, use of animal vaccines is regulated by the United States Department of Agriculture (USDA), not the Food and Drug Agency (FDA). Regulations incorporated in the Animal Medicinal Drug Use Clarification Act (AMDUCA) do not apply to animal vaccines, so using a vaccine in a manner other than stated on the package insert is not considered extra label use; a more appropriate term is "discretionary" use. The VSTA applies only to the preparation, sale, barter, exchange, or shipment of biologics. It does not regulate use of vaccines by veterinarians. Although there are usage guidelines within specific state or federal eradication and control programs and perhaps as isolated rules within some state practice acts, there are no overreaching federal regulations concerning the after-sale use of licensed animal vaccines by veterinarians or lay persons in the United States.

Even so, many veterinarians rely on the vaccine label to protect them. In the past, this was not an unreasonable approach, because by adhering to label instructions, veterinarians could, in most cases, shift the focus of litigation to the vaccine manufacturer. However, in 1996 the United States Supreme Court refused to review the Seventh Circuit Court's decision in *Lynbrook Farms vs. SmithKline Beecham Corp* (117 S.Ct. 178). In that decision, the Circuit Court upheld the contention by the USDA Animal and Plant Health Inspection Service (APHIS) that the VSTA preempted all state court tort remedies that would have the effect of imposing requirements different from or in addition to those imposed by the USDA regarding the safety, efficacy, potency, or purity of a product. In effect, this action eliminated vaccine manufacturers as defendants in all state vaccine tort cases unless it was alleged that the vaccine was improperly manufactured.^{b,c} However, professional negligence and breach of warranty claims against veterinarians using these products were not preempted. As a result, future consumer claims involving vaccines will, in all likelihood, be centered around veterinary malpractice or the failure of veterinarians to adhere to prevailing standards of practice in selecting and administering vaccines, as well as claims that vaccines were given without the proper informed consent.

If, in a court of law, the quality of care provided by a practitioner is being called into question, the practitioner's actions will likely be compared with the prevailing standard of care? a legal term of art that, simply defined, is the care a practitioner of equal experience and training would deliver under the same or similar circumstances. The prevailing standard of care regarding the use of vaccines is in a state of flux, as exemplified by the recommendation of an increasing number of veterinary virologists, veterinary colleges, professional organizations, and practitioners to extend the revaccination interval for certain vaccine antigens. However, by and of themselves, a few published articles or stated opinions of recognized experts do not define a new standard of care; rather, it is their adoption and utilization by a substantial portion of the veterinary community. Vigorous debate within the profession will undoubtedly result in a new standard of care in the selection and use of vaccines. Although many veterinarians will, for various reasons, resist and delay adoption of new protocols, they should know that adherence to

old protocols may, in the light of new knowledge, not protect them as "...conformity to custom is not in itself an exercise of care as a matter of law" (30 AmJur2nd Evidence ?1123). In this uncertain atmosphere, questions about a veterinarian's actions will likely focus on the following types of inquiry: Did the animal need the vaccine? If so, did the veterinarian select the proper agent? Was it in the proper form? Was it given in the proper manner and location? Was the vaccine handled properly? Was it administered aseptically? Was it administered at the proper interval? Did the client give informed consent before the veterinarian vaccinated the animal? Except in the case of herd or population medicine, the answers to these kinds of questions will be unique to the animal being treated.

The current informed consent standard is the "reasonable patient standard." Under this standard, the scope of disclosure is not measured by the physician's standards, but rather by the patient's needs and whether the information is material to the patient's decision (material information is that which a reasonable person in the client's position would use to make an intelligent decision to accept or reject vaccination).^d Under this standard, a veterinarian should disclose the nature of the condition being vaccinated against along with any reasonable dangers within the veterinarian's knowledge that are incident to or may result from vaccination. When vaccination inherently involves a known risk of death or serious harm to an animal, it is the veterinarian's duty to disclose to the client the possibility of such outcomes and to explain in lay terms any significant potential complications that might occur. The veterinarian is also expected to provide information to the client regarding all reasonable alternatives to vaccination. It is the client's decision, not the veterinarian's, to approve or disapprove of vaccination. Once the veterinarian has provided the appropriate information and effectively communicated it to the client, he or she should specifically ask for and obtain the client's consent to the proposed vaccination. In fact, the failure to specifically obtain the client's informed consent could itself be negligent and result in legal liability. For this reason, veterinarians should consider developing consent forms to be signed by owners prior to vaccination of their animals (Appendix 2).

Veterinarians should be cautious in their statements regarding the safety or effectiveness of vaccines. If a veterinarian guarantees that a particular vaccine product is safe or effective, the veterinarian, not the manufacturer, may be liable for breach of warranty.^e This cause of action may not be covered by veterinary malpractice insurance.

The lack of specific rules regarding use of animal vaccines by veterinarians leaves them especially vulnerable to litigation. A veterinarian's exposure to legal liability will be specific to the facts of the case, and though there is no absolute safeguard from litigation, practitioners can go a long way towards protecting themselves by conforming to the standards of practice as they apply to the use of vaccines, by closely adhering to the doctrine of informed consent, and by not providing undue warranty regarding the vaccines they administer.