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 breech 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.

Vaccine Licensing

The VSTA grants authority to the USDA to approve animal vaccines for interstate sale. To be approved, a vaccine must meet requirements for *efficacy, purity, potency,* and *safety.*[65]

Efficacy—Efficacy is a measure of a vaccine's ability to stimulate a protective immune response. Vaccine efficacy is an in vivo measurement, and depending on USDA policy for the disease of interest, it is usually determined by direct challenge exposure of test animals or by measuring serologic responses to vaccination. The USDA has published its approved efficacy determination procedures in the Code of Federal Regulations (9 CFR § 113). The manufacturer must follow USDA codified procedures whenever they exist. The procedures are usually quite specific, regulating the number and species of animals involved in the test, and the method of challenge exposure and evaluation of efficacy.[66]

Codified procedures for evaluating efficacy of different products are similar in many regards. In general, for vaccines to be approved on the basis of measurement of serologic responses, at least 75% of vaccinates must have an antibody titer greater than a set limit when measured a short time (usually 2 weeks) after vaccine administration. For vaccines approved on the basis of challenge exposure studies, in most cases at least 80% of the non-vaccinated controls must develop evidence of disease after challenge exposure, whereas 80% of vaccinates must have evidence of protection (the 80:80 efficacy guideline).[66] Animals are usually challenge exposed 3 to 4 weeks after vaccination. In addition, the number of animals required by either method of efficacy assessment is usually small (eg, at least 20 vaccinates and 5 controls for modified-live FPV vaccines).

The use of codified procedures has the potential to simplify comparisons of the efficacy of vaccines, but unfortunately the USDA does not have codified standards for all of the currently available feline vaccines (eg, FeLV vaccines). If a manufacturer desires to produce a vaccine for which there are no codified efficacy standards, it must submit to the USDA a test procedure it believes adequately demonstrates effectiveness; if the test procedure is approved, the manufacturer may then use that procedure to demonstrate vaccine efficacy. Although the flexibility of this method allows new and novel vaccines to enter the marketplace more quickly than might otherwise be the case, it hampers comparisons of vaccine efficacy, because different manufacturers may have gained approval using different test procedures.