shelters, catteries, or boarding facilities) where disease associated with *B. bronchiseptica* infection has been confirmed. However, the ability of the product to reduce the prevalence of infection or the severity of disease in such environments has not been evaluated.

**Giardiasis**—Infection of cats with the protozoan *Giardia lamblia* is associated with acute or chronic gastrointestinal disease ranging in severity from subclinical to severe.[58,59] Because infected cats shed cysts intermittently, diagnosis of *G. lamblia* infection is often cumbersome and usually requires multiple fecal examinations. Several methods of diagnosis are available, including examination of a fecal smear, the zinc sulfate centrifugation method, and use of an ELISA to test feces.[59] There are currently no approved treatment methods for cats, and although treatment commonly controls signs of disease, it is uncertain that it clears infection.[60] Treatment effectiveness is highly variable, and resistant organisms are commonly encountered.[60,61] *Giardia lamblia* is transmitted via the fecal-oral route; cysts may be ingested from contaminated water, from direct cat-to-cat transmission especially in crowded environments (eg, through mutual grooming), from exposure to contaminated litter boxes, and from consuming prey.[61,62] Giardiasis is a recognized zoonotic disease, but the role of cats in transmission of the organism is not well established.[59,63,64]

A vaccine has recently been licensed by the USDA (Fel-O-Vax Giardia, Fort Dodge Animal Health) as an aid in the prevention of disease associated with *G. lamblia* infection and reduction in the severity of shedding of cysts. This vaccine is composed of quantified, homogenated, and chemically inactivated *G. lamblia* trophozoites, and contains an adjuvant commonly found in other feline products from the manufacturer, but different from the adjuvant in the manufacturer's canine product. The vaccine is approved for use in cats 8 weeks of age and older. At the time of this writing, the vaccine has not been independently evaluated for efficacy, but in studies conducted by the manufacturer to gain vaccine licensure, vaccinates had a statistically significant reduction in severity of clinical signs (diarrhea), duration of cyst shedding, and prevalence of infection (percentage of cats with trophozoites at the end of the trial), compared with control animals. Protection was demonstrated to persist for at least 1 year after vaccination.

*Routine use of this vaccine is* ***not recommended,*** but because vaccinates had less severe clinical disease and shed cysts for a shorter time, it is reasonable to consider vaccination as part of a comprehensive control program in environments where exposure to *G. lamblia* is clinically significant. When parasite exposure is on-going, revaccination at annual intervals is recommended. Some vaccinates may shed cysts subsequent to *G. lamblia* exposure; therefore, proper hygiene and sanitation practices should be implemented even with vaccinated cats. The ability of this product to aid in hastening elimination of endemic infection from multiple-cat environments has not been evaluated.

**Liability Related To Vaccination**

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 extralabel use; a more appropriate term is "discretionary" use. The VSTA applies only to the preparation, sale, barter, exchange, or shipment of biologics.[a] 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 overarching 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