Viral Vectored Vaccines and Potential for Use as Immunocontraception – *Van Kampen*

Vaccination using non-replicating adenovirus-vectored vaccines has been demonstrated to be protective against various infectious diseases in animals. Mice, ferrets, rabbits, chickens, dogs, cats, non-human primates and humans respond with humoral antibodies after immunization with a variety of expressed antigens via oral, intranasal and injectable routes. Immunogenicity against antigenic epitopes of infectious agents has been demonstrated to induce both humoral and cellular immune protection against the relevant diseases. In addition, this technology has been used therapeutically against non-infectious diseases such as cancer, endocrinopathies and even Alzheimer's disease. Multiple preclinical and human patient trials have shown that administration of engineered adenoviral vectors by parenteral, oral and intranasal routes is safe for patients, caregivers and the environment.

We have demonstrated the feasibility of using adenoviral vectors expressing antigens to induce antibodies that block fertility in male and female dogs and cats. However, the application of this scientifically sound, proven technology for companion animal contraception can be inhibited by several complex non-scientific hurdles. For example, biotechnology firms make major investments to develop platform technologies and they own intellectual property to that technology. Funding agencies investing in development of contraceptive vaccines based on such technology must be willing to accept a realistic proportional share of intellectual property in order to attract collaboration from industry.

Safety and efficacy of such vaccines must be approved by the FDA through a process that may cost several million dollars. This high cost of licensing veterinary products, and the perception of low return on product sales, discourages enthusiastic participation by established veterinary product manufacturing and distribution firms. The FDA requires that label claims, such as duration of immunity, be proven in the actual subject species (e.g., dogs and cats) for the actual time claimed. Proving lifelong duration, or even more limited durations of effectiveness beyond 1-2 years, becomes economically challenging. The science of applicable viral vector technology will be described and the non-scientific hurdles potentially limiting success will be elaborated upon.