COULD YOUR ORGANIZATION USE CALCIUM CHLORIDE? NUTS AND BOLTS

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Calcium chloride dihydrate nonsurgical testicular injection ($CaCl^2$) in pure pharmaceutical grade 95-99% ethanol (alcohol) has a long history in the scientific literature, reviewed elsewhere.[1] Following pilot studies in the U.S., India, and Italy, a request to open an Investigational New Animal Drug Application (INAD) file has been submitted to the United States Food and Drug Administration (FDA) by Parsemus Foundation, and a waiver of the $87,700 annual sponsor fee requested under the "barrier to innovation" provision (designed to remove financial barriers to smaller sponsors developing innovative products). If the fee waiver is granted and once the INAD number is received, this would permit research and data-gathering under an established regulatory framework.

However, granting of the waiver is by no means assured, and a sponsor doing research under an INAD does not mean availability for the majority of organizations. Furthermore, because the cost of a start-to-finish FDA approval process (that is, to achieving a New Animal Drug Approval) is beyond the means of the foundation, market availability is not likely unless larger foundations step in. No larger funder has expressed interest to date. This leaves a dilemma for spay/neuter organizations, both foreign and domestic: widespread availability of the sterilant ingredients, affordable formulation, and a growing body of evidence in the literature—yet ambiguity surrounding acceptability of use of novel veterinary treatments that hinders widespread evaluation and potential adoption, all without a corresponding commitment among major funders to the regulatory process that would put such concerns to rest.

American Veterinary Medical Association guidelines emphasize that "The foremost objectives in veterinary medicine are the health and welfare of the patient" and that when considering a novel treatment, "Diagnosis and treatment should be based on sound, accepted principles of veterinary medicine and the medical judgement of the veterinarian" and "Veterinarians should be aware of and abide by local, state, and federal statutes."[2] This presentation seeks to provide information on those aspects and address practical specifics of calcium chloride use, covering three questions: How does calcium chloride injection work? How is it made? And, could your organization use it? It describes ingredients and sterile formulation procedure, demonstrates injection technique with video, answers common questions about pain response, and delineates the issues around use of compounded or non-regulatory-approved treatments in countries with and without functional veterinary drug regulatory agencies. Attendees will leave the presentation with a basic knowledge of how to formulate and use calcium chloride sterilant, as well as a sense of the issues that will determine whether novel non-approved or compounded approaches such as calcium chloride are appropriate and/or permitted in their context. Recommendations for best practices and resources for further research will also be provided.

[1] Alliance for Contraception in Cats and Dogs: Calcium Chloride as a Nonsurgical Sterilant for Male Dogs and Cats: a History and Summary of Research. 2012. V.12.5.12, accessed 6-2013. http://www.acc-d.org/ACCD%20docs/ACCD-CalcChlorReview.pdf.

[2] American Veterinary Medical Association: Policies: Complementary, Alternative, and Integrative Veterinary Medicine. https://www.avma.org/KB/Policies/Pages/AVMA-Guidelines-for-Complementary-and-Alternative-Veterinary-Medicine.aspx, accessed 6/2013.