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Beyond Spaying and Neutering

Highlights of the Alliance for Contraception in Cats and Dogs' Third International Symposium on Non-Surgical Contraceptive Methods for Pet Population Control, November 9–12, 2006

Portland, Oregon, November 29, 2006 – In mid-November, 125 attendees from nine countries convened in Alexandria, Virginia, to assess progress in developing and using non-surgical contraception to manage dog and cat populations. Over the course of three days, world experts in dog and cat reproductive biology presented and assessed the newest research and combined perspectives with experts in animal health drug development. Veterinary leaders from private practice, public health and shelter medicine joined with leaders from animal welfare and advocacy groups, foundation representatives and others. Together, these stakeholders looked at the economic and cultural contexts of controlling reproduction in cats and dogs and delivering programs throughout the world.

News and progress highlights from the symposium are recapped below, with more details available in the event proceedings, available on the ACC&D website at www.acc-d.org by the end of January 2007. With presentations from 37 speakers, additional data presented in poster sessions, plus participant-generated next steps and potential collaborations, the proceedings include a lot of interesting information not covered in this recap!

News, Headlines and Highlights

Products, promising research and regulatory approval

Intervet's **Dr. Marc-Antoine Driancourt** presented data on a new canine contraceptive, Gonazon®, that has just this month received approval in the European Union. This product is a one-year, reversible contraceptive implant for female dogs. While this does not fit the profile of a permanent or long-term tool for dog population management programs, Dr. Driancourt announced some limited data in cats showing that queens had suppression of estrus over an extended period of time – nearly three years so far. This raises the possibility that the product might be useful in the control of feral cat populations, although the expense involved in manufacturing GnRH agonists may be a limiting factor.

Dr. Loretta Mayer of Senestech/Northern Arizona University presented early stage technology for permanent sterilization of female dogs. The drug is an industrial chemical that has been shown to deplete the ovarian follicles and cause sterility in rodents, and there are some preliminary data showing this effect is also seen in dogs. This is a totally new approach and is exciting for its potential for permanent sterility. Dr. Mayer is currently working on dose levels and formulation for single-injection application. Dr. Julie Levy, from the University of Florida, is working with Dr. Mayer on preliminary work in cats.

Mr. Don Landers represented the patent-holder of Neutersol®, a zinc gluconate intratesticular injection for sterilizing male dogs that is approved in the U.S. but is not currently on the market. Mr. Landers announced that the patent holder is working with Abbott Laboratories, which will be manufacturing and distributing the product in the U.S. in the near future. A release date is not yet available.

In a separate presentation, **Dr. Carlos Esquivel** presented newly available results from a field program using zinc gluconate in 10,000 dogs. Esquivel, head of the Mexican VMA and dean of continuing education with the Universidad Autonoma Nacional de Mexico, concluded that their study demonstrated that the product is safe and effective, and can be a valuable tool in getting male dogs sterilized in the field. Overall, sterilization via injection had much greater cultural acceptance than castration in Mexico. Esquivel reported that public health outreach vaccinates 15-18 million dogs annually for rabies, and zinc gluconate has potential for reducing those populations via sterilization. The audience was inspired by the involvement of a man of Dr. Esquivel's stature in this pet population/public health program as well as the breadth of the study and wealth of data collected.

Dr. Kathleen Fagerstone from the National Wildlife Research Center of the USDA presented data on the GnRH vaccine GonaCon™, developed and tested for use in several wildlife species, and the basis for a vaccine being assessed for use in cats. Data is being submitted to the EPA initially for approval for use in deer and other cervids.

Dr. Fagerstone also announced news that as of February 2006, the Environmental Protection Agency (EPA) became responsible for regulating products for non-surgical contraception for use in wildlife. The definition of "wildlife" in this case most likely includes feral cats and dogs. The Center for Veterinary Medicine of the FDA will continue to regulate non-surgical contraceptives for owned household pets. This may generate some confusion, since the EPA might regulate precisely the same product as the FDA CVM but under different standards for different animals. Participants saw opportunities that this might create for a more streamlined regulatory path of products to manage feral animals, but expressed concern regarding the burden this regulatory confusion creates for companies seeking to bring non-surgical contraceptives to market. Conference participants pointed out that in many cases it is hard to distinguish feral cats (EPA oversight) from owned cats (FDA oversight). Various audience members suggested that ACC&D might play a role in lobbying Congress to chart the most sensible and expedient path for potential products to be evaluated by regulatory agencies, although realistically this would be a long and difficult endeavor.

The need for non-surgical sterilants

A variety of panelists looked at need and marketing for these products from various angles:

- **Dr. Hugh Wheir** presented data from Humane Society International estimating 10 dogs per 100 people worldwide. The figure by country ranges from 2 to 35 dogs per 100 people, totaling about half a billion dogs in developing nations with little or no ability to provide surgical sterilization for population control.
- **Dr. Margaret Slater**, a feral cat expert from Texas A&M University, shared that the number of unowned cats (feral and stray) in the U.S. alone is estimated at one-third to one-half the owned cat population. This translates to 30–45 million free-roaming unowned or feral cats. Various presenters offered that there may be opportunity to view this population a bit differently than population control in the owned cat population.

- ACC&D's President **Joyce Briggs** shared analysis that an estimated 12.4 million spay/neuter surgeries are performed in the U.S. annually. About 17%, or 2.1M, are provided by nonprofits or veterinarians as subsidized or "low-cost." At an estimated \$50 subsidy each, that's a cost of \$106 million a year. It is highly likely that at least \$25 per surgery (eventually, far greater!) could be saved through non-surgical methods, saving nonprofits \$53 million per year or, better yet, allowing them to dramatically expand their outreach.
- Although we have used spaying and neutering as a population control technique in animals for many years, the veterinary community has not studied the side effects of these surgeries in any systematic way. Non-surgical alternatives need to be compared to an understood benchmark. Early in the symposium, veterinary research speakers suggested that while spaying and neutering is considered the gold standard, the gold standard may be gold-plated. Research presented on the non-reproductive effects of spaying and neutering point out that there are some increased health risks associated with the procedure that may have been overlooked because the benefits of halting reproduction are so great and surgery has been our primary tool. Health and behavior studies (primarily in dogs) shared a range of conditions that may be affected by spaying and neutering. While mammary cancer is reduced for sterilized dogs and cats, other conditions may be increased, including obesity in dogs and cats, and prostate cancer, urinary incontinence, and cranial cruciate ligament (CCL) rupture in dogs. Data presented by **Dr. Deborah Duffy**, from the School of Veterinary Medicine at the University of Pennsylvania, suggest that a number of undesirable behaviors, such as aggression in female dogs, are worse in spayed or neutered dogs.
- "The Math, the Myth, and Management of Pet Populations," chaired by **Dr. Jan Scarlett** of the Cornell University Shelter Medicine program, was developed in partnership with the National Council on Pet Population Study and Policy¹. Several panelists reviewed best practices in measuring success in population management. This included a new Shelter Population Index (SPI) study under way, presented by **Dr. Margaret Gruen** of North Carolina State University. The study's aim is to establish a valid and consistent estimate or index of shelter dog and cat populations. Several speakers pointed out the need to better understand the role of sterilization in controlling pet populations. Questions were posed about the percentage of sterile animals in a population needed for impact, and balancing the role of sterilization with other strategies (like education, behavior assistance, etc.) to enhance humane treatment of dogs and cats.

ACC&D's Action Plans

Interactive sessions throughout the symposium gathered input from various stakeholder groups (e.g., veterinarians, pharmaceutical companies, researchers, animal welfare organizations, funders) on what they need to advance this work and what actions they recommend that ACC&D take.

ACC&D shared concrete plans to advance its mission of "expediting the successful introduction of technologies to non-surgically sterilize dogs and cats and to support the distribution and promotion of these products to humanely control cat and dog populations worldwide." Plans include developing public/private partnerships to help bring new products to market. **Katherine Moldave**, MBA, of AlcheraBio discussed various types of partnerships that have been successful in human-health drug development. ACC&D President **Joyce Briggs** discussed "The New ACC&D" and the Agenda for Advancement and Priorities for Product Development:

The Alliance for Contraception in Cats and Dogs Agenda for Advancement

1. Seek partnerships and take action to get zinc gluconate used in effective population control programs in the U.S. and worldwide to save the lives of dogs.
2. Build partnership with holder of early stage technology with potential for permanent non-surgical sterilization for female dogs and cats. (It was announced that a strategic partnership with Senestech is being explored in order to advance their technology in accordance with ACC&D's mission.)
3. Raise \$10 million to advance both male and female technology projects.
4. Identify and build demand for non-surgical sterilants from pet keepers, animal welfare organizations, and veterinarians, with outreach primarily through strategic alliances.
5. Conduct consumer research to determine the market opportunity for these products, and for guidance on the best messages to effectively market both the product concept and products to key audiences: pet keepers, veterinarians, and animal welfare organizations.
6. Expand ACC&D's advisory board with additional members experienced in pharmaceutical development to assist researchers and funders to best direct resources.

Priorities for Non-Surgical Products for Pet Population Control

- Approved by regulatory agencies as safe (for animals and for the humans administering) and effective.
- Permanent, though there may be some opportunity for long-term (3+ years) products.
- Deliverable in a single injection or treatment.
- Products available for effective use in both males and females, dogs and cats.
- Documented effects on behavior and health.
- Can be provided at affordable rates for use in indigent or low-income client populations.

New Initiatives with Participants

The meeting closed with a half-day session on plans and collaborations to move this work forward, with participants generating ideas and starting personal action plans. The many ideas included creating a "Collaboration Bank" of individuals, organizations and capabilities, a video on successful use of non-surgical sterilants, collective work to answer specific research questions, and collaborations around educating stakeholder groups about raising funds for this work.

The participants were enthusiastic in their responses to this unique meeting, at which the animal health industry, the animal welfare community, and academics from across the globe gathered to plan for action on the pressing problem of worldwide pet overpopulation. Of the respondents who completed an evaluation, 77% rated the symposium as "Excellent" (and 21% rated it as "Good").

Among industry attendees, Pfizer Animal Health, Virbac, Peptech Animal Health, Abbott Laboratories, Dechra and Intervet Pharmaceuticals were represented, as were small companies such as Senestech, Amplicon Express (developing a GnRH vaccine) and Reprostat (developing lytic peptides). Government attendees included representatives from USDA, and the FDA Center for Veterinary Medicine. AVMA was represented, as was the American Animal Hospital Association, which also sponsored the event.

Animal welfare organizations in attendance included ASPCA, HSUS, American Humane Association, Best Friends Animal Society and Massachusetts SPCA, as well as regional and local groups.

Special Thanks

ACC&D's Third International Symposium would not have been possible without the support of its sponsors. Many thanks to Erika Brunson and the PK Foundation, ASPCA, The Glaser Progress Foundation, Humane Society of the United States, Petfinder.com Foundation, American Animal Hospital Association, American Humane Association, Morris Animal Foundation, Pegasus Foundation, and Peptech Animal Health. The National Council on Pet Population Study and Policy¹, representing a diverse range of 12 national animal organizations, was both a sponsor and program partner.

Please note:

A comprehensive list of speakers and attendees, summaries and visuals from presentations, and outcomes will be provided in the proceedings document available to view or download free of charge at www.acc-d.org by the end of January 2007.

¹The National Council on Pet Population Study and Policy consists of the following member organizations: American Animal Hospital Association; American Association of Feline Practitioners; American Humane; The American Pet Products Manufacturers Association; American Society for the Prevention of Cruelty to Animals; American Veterinary Medical Association; Association for Veterinary Epidemiology and Preventive Medicine; Cat Fanciers' Association; Humane Society of the United States; Massachusetts Society for the Prevention of Cruelty to Animals; National Animal Control Association; Society of Animal Welfare Administrators.

Quotes from Symposium Participants

“Last weekend was really life-changing; because of the symposium I've now decided to do Ph.D. research on a topic involving non-surgical sterilization.” – *Holly Anderson, student, Cornell University College of Veterinary Medicine*

“In general I found the conference to be very valuable, even to me, with my interests in wildlife rather than cats and dogs. I thought you did a very good job of ferreting out the current research that has application to companion animals.... The format was very good, too, better than most conferences of this type. There was ample time for informal palaver between various parties and that is always the greatest worth of meetings.... I thought it was one of the more valuable meetings I have attended in recent years. I'm glad I could contribute and I wish the ACC&D the best of luck and good fortune in its important endeavor.” – *Jay F. Kirkpatrick, Ph.D., Director, The Science and Conservation Center, Billings, Montana*

“The most valuable part of the symposium was that ACC&D opened the doors to other people from other parts of the world.” – *Dr. Carlos Esquivel, Mexico*

“It was really great. I feel energized and have more purpose in what I am doing. It was especially helpful and impressive to see and hear the non-scientists describing the problems and giving important input that would not otherwise be heard.” – *Patrick Devine, Senestech, Inc.*

“I feel/think that this conference achieved a breakthrough this year. I felt a genuine new energy of unity among all the participants.... Hearts and minds seemed more open, egos seemed more cooperative and a feeling that we were all on the same team with a shared dream and we need each other to materialize our goals.” – *Dr. Hugh Wheir, Animal Alliance, New Mexico*

“Thank you so much! I am empowered and energized once again by your conference. For me it's a dream to be able to talk for two days about this work and the future possibilities. You have speeded up Animal Balance's work by years. Of course I am terribly impatient for this new technology to be available as we

have to lug ax machines and H tanks on tiny little boats from island to island and it is not efficient. We can do so much more if we have a backpack full of injections! If there is any way that I can help ACC&D or others replicate this kind of work, please let me know. Thank you once again for all your hard work. The conference was the highlight of my career. Two years ago, I came to the conference looking for non-surgical techniques and so it was wonderful to come back and say we did it and it's working. Thank you all!" – *Emma Clifford, Executive Director, Animal Balance, California*

"The brain trust present at this meeting was exceptional and I was honored to attend."
– *Dr. Apryl Steele, Denver, Colorado*

"Thank you, thank you. It was a fantastic symposium!" – *Kelly Coladarci, Yucatan, Mexico*

"The most valuable part of the symposium was various professionals (scientists, vets, epidemiologists, funders, humane workers) all learning more from each other. That's the only way to really see the big picture!" – *Dr. Lynne Swanson, Virginia*

"This was a good meeting which brought together folks with various backgrounds and interests and got them speaking with each other. It is a great way to accelerate progress toward a goal if everyone works together." – *Dr. Gary Killian, Pennsylvania*