



AAVPT NEWSLETTER

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Pharmacology and Therapeutics

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From The President



A belated happy new year to all AAVPT members. If 1997 is anything like 1996, it will be an active year for veterinary pharmacology. In January, I was invited to participate in an expert consultation on risk management convened in Rome under the joint auspices of the Food and Agriculture Organization and the World Health Organization. The consultation was charged to develop a document which would define the role of governments in establishing acceptable levels of risk from food-borne hazards and to provide guidance for managing those risks. The importance of the consultations was underscored by the presence of a representative from the World Trade Organization who stated that the WTO would recognize standards developed by expert bodies as the basis for resolving international trade disputes. The consultation was comprised of approximately 35 experts from countries around the world, but of particular interest was fact that more than half of the experts were veterinarians. When I realized this, I immediately felt an overwhelming sense of pride that my profession was held in such high esteem throughout the world. This feeling was quickly tempered, however, when I realized that of the five U.S. government officials present, I was the only veterinarian.

The number of veterinarians serving at high level positions in the U.S. government is declining. It was only a few years ago that Dr. Lester Crawford was Administrator of the USDA Food Safety and Inspection Service. When he resigned, he was replaced by an animal scientist, followed by a lawyer, followed by a chemical engineer. Last summer, Dr. Lonnie King resigned as Administrator of the USDA Animal and Plant Health Inspection Service. He was replaced by a lawyer. I am personally acquainted with all of these non-veterinarians, and I hold them all in high regard, but I remain troubled by the fact that the role of veterinarians in shaping national policy is diminishing in the U.S. at the same time that it is growing throughout the rest of the world. All of this may be nothing more than a recent down turn in the government cycle, but if it continues, our profession will suffer from a loss of public esteem that will be very difficult to regain.

On a lighter subject, on February 12 a live satellite teleconference was held in Rockville, MD to answer questions from veterinarians about the Animal Medicinal Drug Use Clarification Act. The three hour telecast which was co-sponsored by the FDA, AVMA, and the Association of American Veterinary Medical Colleges, included a live studio audience with representatives from AVMA's Council on Biologicals and Therapeutic Agents, American Association of Bovine Practitioners, American Association of Swine Practitioners, American Association of Wildlife Veterinarians, the Food Animal Residue Avoidance Databank, the Animal Health Institute, the American Feed Industry Association, and other allied organizations. In addition to questions from the studio audience, live phone in questions were answered from veterinarians located at downlink sites throughout the U.S. By all accounts, it was a unique and successful program. A similar program on the subject of Veterinary Feed Directive drugs will likely take place later this year.

Finally, I wish to extend my thanks and congratulations to Dick Teske who retired from the FDA on January 3. In addition to being an active member of AAVPT, Dick was active in the American Academy of Veterinary and Comparative Toxicology, the American Board of Veterinary Toxicology, the U.S. Pharmacopeia, and other related organizations. Throughout his career, Dick's contributions to veterinary pharmacology were substantial in the areas of research, regulatory science, and government policy. Upon his retirement, Dick relinquished all of his duties except that of author of the AAVPT's "News from Washington" column in our AAVPT Newsletter. On a personal note, I will miss very much working on a day-to-day basis with Dick Teske.

- Stephen Sundlof

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Formal Notice of AAVPT's Annual Business Meeting

Date: Thursday, 22 May 1997

Place: ACVIM Forum - Walt Disney World Dolphin Hotel
Lake Buena Vista (Orlando), Florida

Time: 7:00 p.m. (See ACVIM Program for meeting room.)

Secretary-Treasurer's Report

I would like to welcome the following new AAVPT members. Michael Apley, Terrence Clark, Robert Walker, Carlos Lanusse, Philip Inskip and Jonathan Hare were elected as Fellows. Tomas Martin-Jimenez was elected as a new Student Member. Upgrading to Fellow status were Sarah Gardner and Carol Davis. The addresses of these members are listed below.

The 1997 AAVPT dues are due now. Response so far has been very good. If you haven't paid your 1997 dues, please send them in as soon as possible. Annual dues are \$35 for Fellows, \$20 for Associate Fellows, and \$10 for Student Members.

Please renew or start your subscription to the Journal of Veterinary Pharmacology and Therapeutics. The 1997 subscription price is only \$55.00 for AAVPT members. This is a special price, so I encourage everyone to subscribe. This is a good time to order your subscription - the first issue in 1997 has just been mailed. If at any time you have not received JVPT issues that you believe you should have received, please notify me as soon as possible. Blackwell (the publisher) is quite good about sending back issues and rectifying problems. It really is important for people to pay their dues and subscriptions early in the year, so I don't accidentally remove your name from the JVPT mailing list when you were intending to subscribe. If you're not sure if you've subscribed for 1997, call me (860-441-7361), or even better, send me an e-mail message (ann_d_jernigan@groton.pfizer.com). Because I am out of the office often, I respond most quickly to e-mail messages.

Contributions to the AAVPT awards fund (used for student awards and service awards) may be made at any time and may be included with your dues or subscription. I would like to thank the numerous people who have contributed this year. So far, \$400 have been contributed to the Awards fund. This is terrific, but we would like to be able to fund even more awards, so I urge all AAVPT members to consider making a contribution.

AAVPT is in good shape financially at this time. We have \$12,528 in our checking account. On our AAVPT membership list, there are 146 Fellows, 30 Associate Fellows, 10 Student Members, 8 Distinguished Fellows, and 8 Emeritus Fellows. Of the dues-paying members, so far 93 Fellows, 13 Associate Fellows, and 5 Student Members have paid in 1997. We really need to hear from our other members!

We will be electing new officers soon, so watch your mail for the ballot.

Addresses of New/Revised Members

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- Ann D. Jernigan

AAVPT & ACVCP Program Committee Updates

The AAVPT/ACVCP are jointly sponsoring a one day program addressing anti-inflammatory and analgesic drug therapy to be held on May 22, 1997 in Orlando, Florida in conjunction with the 15th Annual Veterinary Medical Forum of the American College of Veterinary Internal Medicine. Professor Peter Lees of the London Royal Veterinary College will provide the opening "state of the art" presentation on "Inflammation and the Pharmacology of Anti-inflammatory Drugs." Information concerning registration at the ACVIM meeting is available by calling (800) 245-9081 or by E-mail at: <acvim@aol.com>; lodging is available by calling (800) 227-1500 (be sure to mention that you will be attending the ACVIM Forum). A program synopsis follows below:

Inflammation and Pain

Morning Moderator: Dr. Charles R. Short (LSU)

Session	Title	Speaker
1.	Inflammation and the Pharmacology of Anti-inflammatory Drugs	Prof. Peter Lees (U. of London)
2.	Continuation	Prof. Peter Lees (U. of London)
3.	Newer Approaches to	Dr. Steven Kamerling (LSU)
4.	Pharmacology and Use of Opiates & Alpha-2 Antagonists	Dr. William Tranquilli (U. of IL)

Afternoon Moderator: Dr. Ted Whittam (U. of IL)

5.	Pain Management in Equine Colic and Acute Laminitis	Dr. James Moore (U. of GA)
6.	Assessment and Management of Acute pain	Dr. Bernie Hansen (NCSU)
7.	Management of Chronic Pain	Dr. Elizabeth Hardie (NCSU)
8.	Practical Use of Analgesics	Dr. Mark Papich (NCSU)

The AVMA has invited AAVPT/ACVCP to provide a one-day program on "Advances in Veterinary Pharmacology" on July 22, 1997 at the national AVMA meeting in Reno, Nevada. Antimicrobial therapy and bacterial resistance, sedatives and reversal agents, newer nonsteroidal anti-inflammatory drugs, and nitric oxide will be addressed. A program synopsis follows below:

Advances in Veterinary Pharmacology

Moderator: Dr Dawn Boothe

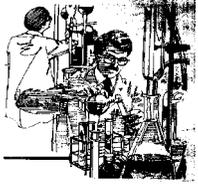
Time	Topic	Speaker
8:30-10:00	Antimicrobial Resistance: Origins and Trends	Dr. Patricia Dowling
10:15-10:45	Clinical Application of Sensitivity Data	Dr. Patricia Dowling
10:45-11:15	Rational Antimicrobial Therapy	Dr. Patricia Dowling
11:15-12:15	Sedatives and Their Reversal	Dr. Steven Kamerling
1:30-3:00	Inflammation and New NSAIDS	Dr. Steven Kamerling
3:45-5:15	Nitric Oxide: The Good, the Bad, and the Ugly	Dr. Rustin Moore

Dr. Rick Vulliet at the School of Veterinary Medicine in Davis California is in the process of organizing the Eleventh Biennial Symposium of the AAVPT to be held on the Monterey Peninsula during the third or fourth week of June 1998. The program for the 3-3.5 day program is still being developed, and Rick invites your suggestions for topics and speakers. Please convey your ideas to him by calling (916) 752-7409, sending them by E-mail to: <prvulliet@ucdavis.edu>. Graduate students will be encouraged to attend, and a poster session will be provided. There will be many opportunities for relaxation and tourism by conferees and their families. This promises to be a very enjoyable symposium, and we are looking forward to a big turnout of our membership. Future issues of the newsletter will bring you additional information as it becomes available.

- Gary Koritz (AAVPT)
- Charles R. Short (ACVCP)

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News From the Pharmaceutical Industry



Merk and R. Poulenc have announced that they will combine their animal health and poultry genetics businesses to form a 50:50 joint venture called Merial. With combined revenues of \$1.7 billion for 1996, Merial will be the largest company in the animal health and poultry genetics

industries.

Two orphan drug NDA's were recently filed. Antizol (fomepizole), an injectable antidote for ethylene glycol poisoning was submitted by Orphan Medical, and Provigil (modafinil), a psychostimulant for narcolepsy, by Cephalon. Antizol inhibits the enzyme alcohol dehydrogenase which is responsible for the metabolism of ethylene glycol to toxic metabolites. Available data indicate that there were 4,792 ethylene glycol exposures in 1994 resulting in 32 deaths.

SmithKline Beecham's new malaria vaccine developed in conjunction with Walter Reed Army Institute of Research has shown encouraging results in a preliminary study in human volunteers. The vaccine (SBAS2), which is recombinant, has achieved a high degree of protection against the pre-erythrocytic stages of the human malaria parasite. The results show that immunization with a single sporozoite antigen can produce full protection of the majority of recipients, and is deemed a considerable advance in the field.

- Elliot Piperno

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Seventh EAVPT International Congress

You are cordially invited to come to Madrid, Spain, July 6-10, 1997 to take part in the Seventh EAVPT International Congress. The meeting will include five plenary lectures and 14 keynote lectures, oral and poster communications, and an exhibition (products, instruments, and publications). The aim of the Congress is to bring together people interested in the field of Veterinary Pharmacology and Toxicology and to spread knowledge which ultimately promotes improved scientific practices in these areas. The meeting will be held at the Palacio de Congresos, which is located on the Castellana Avenue in the heart of Madrid. We hope to be able to offer a number of attractive events in the social program.

The Scientific Sessions will present information on the following research topics: (1) **Biopharmaceutics and pharmacokinetics** (Delivery and disposition of drugs; Pharmacokinetic pharmacodynamic models; Bioavailability bioequivalence studies; and Drug pharmacokinetic interactions); (2) **Drug Metabolism** (Drug -induced changes in metabolism; Drug metabolizing enzymes; Peroxisome

proliferation; Drug metabolism is safety evaluation; In vitro alternative models in drug metabolism studies); (3) **Clinical pharmacology and therapeutics** (Clinical trial design, Efficacy testing for minor species, Age-related pharmacology, Antimicrobial agents, Endo- and ectoparasiticide agents, Inflammatory mediators and anti-inflammatory agents, Anesthetic agents, Topical products, Bioengineered products, Production-growth enhancement agents, Probiotics); (4) **Pharmacology and therapeutics in various species** (Fish, Birds, Zoological and Wild Life species, Minor ruminant species, Laboratory animals); (5) **Systemic pharmacology** (ANS and CNS, Cardiovascular, Respiratory, GI, Urinary, and Reproductive); (6) **Toxicology** (Toxicokinetics, Cytokinetics, Drugs, Pesticides, Mycotoxins, Marine & other toxins, Metals, Ectotoxicity); (7) **Regulatory matters** (Veterinary medicines, Marketing, Food additives in animal nutrition, Drug residues, Environmental risk assessment, Bioengineered products, Pharmacovigilance, Toxicovigilance)

For further information please contact the **Congress Chairman: Prof. Dr. Arturo Anadon**, Seventh EAVPT International Congress, Department of Toxicology, Faculty of Veterinary Medicine, Universidad Complutense de Madrid, 28040 Madrid, Spain [Telephone: (34-1)-3943834; Fax: (34-1)-3943840; E-mail: <anadon@eucmax.sim.ucm.es>], or the **Technical Secretariat: Grupo 7 Viajes**, Edificio ECU, San Romualdo, s/n, 28037 Madrid, Spain (Telephone: (34-1)-7540012; Fax: (34-1)-7543200).

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Announcing the Third Course on Industrial Toxicology and Pathology, May 19-21, 1997, Urbana, Illinois.

Course directors for this special program are: Wanda Haschek-Hock, BVSc, PhD, DABT, DACVP, Professor of Pathology and Irene Cooke, DVM, PhD, Lecturer in Pharmacology, University of Illinois at Urbana-Champaign.

This course addresses current global issues in the rapidly advancing fields of industrial toxicology and pathology, focusing on experimental design and evaluation, safety assessment, and regulatory issues associated with product development. The course offers an educational update for professionals whose responsibilities require knowledge of toxicology and pathology, and who are employed in pharmaceutical, chemical and consumer products industries; government organizations, or contract laboratories.

It is intended to enhance participants' skills in interpreting animal safety studies and facilitate their interactions with federal regulatory agencies. Registration: \$650 by April 15, 1997, \$735 after April 15, 1997, and \$250 for currently enrolled graduate students (w/letter from advisor). Please contact: Nancy Mulvany, Phone 217-333-2888; Fax

217-333-9561; E-mail <nmulvany@uiuc.edu>. For more information see - <<http://www.conted.ceps.uiuc.edu/CI/tox>>.

- Irene Cooke

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Residency/Graduate Study in Clinical Pharmacology - University of Illinois

The Department of Veterinary Biosciences, College of Veterinary Medicine, University of Illinois, and the Animal Health Division of Pharmacia and Upjohn Company, jointly announce an opening for a veterinarian interested in clinical training and graduate study in veterinary clinical pharmacology. This unique residency/M.S. program will be of three (3) years duration. An option to extend this to a Ph.D. program is available.

The first 12 months will be spent with case-care responsibility in the Veterinary Teaching Hospital at the University of Illinois, primarily with the major species of interest to the candidate. Subsequently, two years will be devoted to research in clinical pharmacology, pharmacokinetics, drug metabolism, analytical methods, or other related field of study. One of these two years will be spent at the Animal Health Division facility of Pharmacia and Upjohn Company in Kalamazoo, Michigan. Prescribed and elective graduate course work will be completed during the first two years of the program. This program will satisfy the credential requirements to be admitted to candidacy for examination by the American College of Veterinary Clinical Pharmacology (ACVCP). A stipend is available beginning from \$18,250 to \$20,500, depending upon experience, with step-wise salary increases. Additional benefits include: Tuition and fee waiver, University Staff benefits, assistance to attend one major scientific meeting per year, and assistance with expenses of relocation from Champaign/Urbana, IL to Kalamazoo, MI during the program.

Qualified applicants will: Have a D.V.M. or equivalent degree, and be licensed to practice in their own state or country, have completed a 12-month rotating internship or equivalent practice experience, satisfy the requirements for entry to the Graduate School of the University of Illinois and the requirements for graduate students in the Department of Veterinary Biosciences, and demonstrate a desire for a career in veterinary clinical pharmacology. The position is available for July 1, 1997, and the application deadline is March 30, 1997. For further information or application forms, please contact: **Dr. Ted Whittem**, Department of Veterinary Biosciences, LAC210,1008 W. Hazelwood Dr., Urbana, IL, 61801. Telephone: (217) 333-4246. Internet E-mail: <whittem@uiuc.edu>.

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News From Washington



FDA Publishes Final Rule on Extra-label Drug Use in Animals

The final rule implementing the Animal Medicinal Drug Use and Clarification Act of 1994 (AMDUCA), was published in the November 7, 1996, Federal Register. This regulation, which went into effect on December 9, 1996, provides veterinarians with greater flexibility in the use of approved drugs in animals.

Prior to enactment of AMDUCA, the Federal Food, Drug, and Cosmetic Act provided that approved animal drugs must be used only in strict accordance with the directions provided in the approved labeling of the drug.

Under AMDUCA, the FFD&C Act now permits veterinarians to use approved drugs (both animal and human) in an extra-label manner when the health of their patients is immediately threatened and suffering or death might result without such treatment. However, there are still a number of needs in veterinary medicine that can be met only by using drugs in an extra-label manner that are not covered under AMDUCA. For example, the extra-label use of drugs to enhance the reproductive performance of food animals is not permitted under AMDUCA.

AMDUCA also includes a number of provisions that permit the Agency to restrict extralabel use in certain circumstances. For example, if there is a finding that there is a reasonable probability that an extra-label use may present a risk to public health from drug residues in animal-derived food, the Agency may establish, by regulation or order, a safe level for a residue resulting from such use and may require that an analytical method to detect such residues be developed. If, after allowing for public comment, FDA finds a particular extra-label use represents a public health risk or that no analytical method has been developed, the Agency may prohibit such extra-label use. Currently, use of the following drugs in food-producing animals is prohibited:

- M** Chloramphenicol
- M** Iprnidazole
- M** Clenbuterol
- M** Nitroimidazoles
- M** Diethylstilbestrol (DES)

- M Furazolidone (except topical)
- M Dimetridazol
- M Nitrofurazone (except topical)
- M And for lactating dairy cattle, all sulfonamide drugs except those approved for such use

Title 21 of the Code of Federal Regulations is now amended to add a new part 530, titled "Extra-label Drug Use in Animals." A link to the text of the rule is available for review or downloading on CVM's Internet Website at <<http://www.cvm.fda.gov/>>. The document as it appears in the Federal Register is also available in PDF format from the U.S. Government Printing Office's Access search screen at: <http://www.access.gpo.gov/su_docs/aces/aces140.html> (search on extra-label).

-Richard H. Teske

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Six AAVPT members who reside in countries outside of the United States did not receive their November 1996 issue of our AAVPT Newsletter, since six of the envelopes containing them were returned to me by the U.S. Postal Service with their address labels missing.

Consequently, I had no way of knowing at the time who did and who did **not** receive their copy. If you are one of the persons residing outside of the United States who did **not** receive the last issue (November 1996), please let me know as soon as possible, kindly provide me with your current address, and I will send you a copy. Please accept my apology, but the situation was completely beyond my control, and unfortunately, this is the best way that I could think of to correct this difficult situation.

It is not at all unusual for AAVPT members to change their mailing address and/or place of employment without making appropriate provisions for their mail to be forwarded. Over the years, it has happened more times than I can or care to remember. In such cases, their newsletters have also been returned to me undelivered, and I have tried my best to find a new address for them. Sometimes I get lucky, and sometimes their new address simply remains a mystery until we finally hear directly from the person concerned. If **you** have recently changed your address, or if **you** anticipate doing so in the near future, **please notify** our Secretary/Treasurer, Dr. Ann D. Jernigan, so she can update AAVPT's computer files, to reflect the change. Only by doing so can you assure yourself of receiving your copy of each AAVPT Newsletter and any other important AAVPT-related mailings. Your help and cooperation in this regard is absolutely essential in order for us to keep our avenues of communication open to you, so please do your part to make our job just a little bit easier in such situations.

At this point, I would like to take a moment to

congratulate Dr. Dick Teske upon his retirement from CVM-FDA, and to wish him well as he enters yet another phase of his long and distinguished career in veterinary medicine and government service. Dick has faithfully kept us informed about important happenings in Washington and how they impact on our profession since the very inception of our AAVPT Newsletter. He has been a good friend and colleague of mine for many years, and I am most pleased that he has kindly and graciously agreed to continue writing his "News from Washington" column for future issues of our newsletter. We all owe Dick a huge debt of gratitude for his loyal service these many years. While he is still very much "in harness," I would also like to thank my good friend and colleague, Elliot Piperno, for his continued service (also from the inception of our AAVPT Newsletter) as well, by providing us with information about happenings and new developments within the pharmaceutical industry. People like Dick and Elliot, and their willingness to become and stay involved in AAVPT-related activities, are what make our organization so special. They, along with many others over the years, have continued to help me keep you better informed about AAVPT matters and other information of interest to the profession. As I begin yet another year as the editor of your newsletter, I salute and thank each of you.

- Carl E. Aronson

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(Editor's Note: Please record the change in my E-mail address, listed above, from the one that appeared in previous issues of the AAVPT Newsletter. E-mail sent to the old address is presently being forwarded to the new address for now, but I am not sure how long that will service will be continued, so please use the new one for all future E-mail messages directed to me.)