



# AAVPT NEWSLETTER

The American Academy of Veterinary  
Pharmacology and Therapeutics

Volume 20, Number 1

February 2001

## From The President



**T**ime flies when you are having fun! It's hard to believe that this is the last newsletter update prior to the election of officers and the completion of my time as President of the AAVPT. I must say it has been a humbling experience, as we have seen and foresee so many changes in the discipline and the profession. I am indebted to the officers and Councilors who have served the Academy and assisted me in so many ways. My thanks in particular to Debbie Kochevar, who has served as Secretary/Treasurer during my tenure as President, and to Cory Langston, who will assume the helm of the Academy in May 2001. My objectives are to make that transition smooth and continue to serve the Academy in whatever ways are considered best by the new officers and Councilors, and that are consistent with my primary responsibilities to my employer.

I am also deeply indebted to Carl Aronson who, after many years of service to the Academy, has elected to move his membership to Emeritus Fellow at the completion of this newsletter. Carl has served the profession and the discipline of veterinary pharmacology in so many ways over the years. A past President of the Academy, he has continued to serve the AAVPT as AAVPT Newsletter editor, historian, Constitution and Bylaws Subcommittee chair, and archivist (just to name a few). Carl, on behalf of the entire Academy, our deepest thanks for your faithful service to the AAVPT and steadfast commitment to veterinary pharmacology since the inception of the AAVPT in 1978. Your retirement from your job did not deter your commitment to the Academy for many years, and Emeritus Fellow status is well earned. Best wishes for a long and happy retirement!

Watch closely on the AAVPT website ([www.aavpt.org](http://www.aavpt.org)) for a facelift that will include new links, newsletter postings, directory listings, and additions that should keep us linked more effectively to each other as well as to veterinary pharmacology and therapeutics worldwide. Monitor the website for updates on the Biennial Symposium and Business meeting, as well as other late-breaking news.

Speaking of the electronic age, don't forget to cast your

votes for the bylaws changes (many of which are designed to allow electronic communications rather than stipulate traditional mail communications). The Council believes these changes will allow for more effective, more complete, and more responsive communication and service to the discipline and profession. As we have recently seen with the presidential election in the United States, every vote counts.

Make your plans now for the AAVPT Biennial Symposium in Denver in late May 2000. This will be our inaugural joint meeting with the ACVIM, and should provide both basic and clinical perspectives to the AAVPT meeting and contacts with the internists with whom so many of us interact routinely. Both the AAVPT and ACVCP Annual Business meetings will be held at this venue. See the Program Committee report elsewhere in this newsletter for specific details.

What are my primary concerns for the discipline and profession in the future? I believe the move to genomics and molecular biology is valuable, but whole animal physiologists and pharmacologists are a vanishing breed. We must find ways to foster interest, education, and funding in veterinary physiology and pharmacology. In addition, I believe veterinary pharmacology needs to work with the food animal production industry to foster prudent antimicrobial use and, more importantly, improve biosecurity measures that can curb the spread of antimicrobial resistance in food-borne pathogens. I intend to serve the Academy any way that I can to positively impact these areas of concern in the future.

Last, I am quite confident that the AAVPT will continue to be a viable and valuable organization in the future. The current President-Elect, Cory Langston, has the outstanding leadership skills and knowledge of the veterinary profession and discipline of veterinary pharmacology to lead the Academy exceedingly well in the next two years. The best is yet to come!

- Scott Brown

\* \* \* \* \*

## Secretary - Treasurer's Report

**H**appy New Year. I hope everyone had a safe and happy holiday.

Dues notices and ballots should have arrived prior to the holidays for all members. If you have not received this mailing, please contact me as soon as possible. Dues remained unchanged (\$35 Fellow, \$20 Associate Fellow, \$10 Student Member), but JVPT subscriptions increased to \$74. Even if you are an Emeritus Fellow, and therefore are not paying dues, please complete and return the dues statement if any of your contact information has changed. If you previously notified me that you would be renewing your JVPT subscription, please be sure to include the JVPT subscription costs in your payment.

Remember that funding for AAVPT Awards (Service, Teaching, Research, and Student) depend upon donations. Please consider including a donation to the Awards Fund with your dues payment. We would like to thank those members who have already contributed to the awards fund this year including: W. Kay, S. Sundlof, G. Koritz, M. Ehrich, S. Longhofer, J.W. Oliver, D. Boothe and W.R. Lance.

The AAVPT web site has very recently been transferred to Texas A&M University where it will be maintained for the foreseeable future. We are planning several additions which we hope to accomplish by the time you read this newsletter! All newsletters and other communications, the directory, application forms, the Constitution and a variety of useful links will be added to the site. Please help us update the membership database for future directories by providing current contact information. We will try to incorporate address changes on the web site at regular intervals to serve the membership in between directory updates.

I hope to see you at the 12th Biennial Symposium in Denver on May 22 - 24, 2001. The social, basic science, and business meeting parts of the program will occur on May 22- 23 at the Adam's Mark Hotel just prior to the ACVIM Forum. The clinically oriented part of the program will be given the afternoon of May 23 and the morning of May 24th as part of the ACVIM Forum. Please see the Program Committee Report in this newsletter for further details.

Our bank account stands at \$14,629.93 as of January 18, 2001. Dues and journal payments are arriving daily. We anticipate a payment of approximately \$3500 - 4000 to Blackwell Science later this year for JVPT subscriptions, as well as expenses associated with the 12th Biennial Symposium in Denver. Initial expenses for changing and updating the web site will probably run approximately \$500.

I have enjoyed serving the AAVPT as Secretary-Treasurer over the past 2 years. Please continue to contact me with AAVPT business until we transition to the new officers (sometime in June 2001). Although I will not be continuing as Secretary-Treasurer, I will be assuming responsibility for maintenance of the AAVPT web site. Please feel free to contact me with items that you would like to see posted to the web, or to suggest ongoing features that we might add to the site design. Have a safe and happy year in 2001.

- Deborah Kochevar

\* \* \* \* \*

## Congratulations

**W**e all extend our congratulations and best wishes to the following AAVPT colleagues listed below who have been recognized for their accomplishments.

**Dr. Mike Apley** received the "AABP/Hoffman LaRoche Award of Excellence" at the AABP meeting.

**Dr. Jeff Wilcke** has been named to a newly endowed professorship, the "Dorothy A. and Richard G. Metcalf Endowed Professorship in Veterinary Medical Informatics."

\* \* \* \* \*

## Journal of Veterinary Pharmacology and Therapeutics

**T**he Journal of Veterinary Pharmacology and Therapeutics held an Editorial Board meeting in conjunction with the Jerusalem EAVPT Congress on July 30, 2000. This provided an excellent opportunity for the board members from both sides of the Atlantic to contemplate the state and future of the journal. Submissions are up 15% from 1999. Rejection rates have stabilized for both editors to the range of 33% in the US and 25% in Europe. The quality of the journal is improving as judged by an increase in the ISIS "Impact factor." There was a consensus that the journal should renew its call for quality review articles and strengthen its therapeutics section. Thus please support your journal by submitting therapeutics oriented work to JVPT, and any ideas on timely review articles to me for consideration.

A few new sections will be added. **First**, there will be a "Letters to the Editor" section implemented immediately to foster open dialogue on controversial issues in our field. **Second**, in 2002 we will implement a "Rapid Communication" section that will have a different and expedited review process. Please note that the current "Short Communication section" relates more to content than review time.

Finally, I would like to announce the appointment of two new Editorial Board members: Drs. Marilyn Martinez and Dr. Ted Whitem. Welcome! I would like to thank our exiting members Drs. Jean Powers and Wayne Schwark for their outstanding service to the journal.

- Jim E. Riviere

\* \* \* \* \*

## News Update From the

## Pharmaceutical Industry



The Animal Health Institute (trade association of animal pharmaceutical companies) reported that New Animal Drug Applications (NADA) may take an additional 1.5 years beyond what it normally takes FDA to complete their reviews. This was based on a recent survey by AHI of their members for the years 1998-2000. It was conducted to measure the severity of the current review delays at FDA's Center for Veterinary Medicine. The AHI analysis also concluded that 88 % of original NADAs (new drugs) and 22% of supplemental NADAs (e.g., add species, add a claim) were overdue. These delays are unprecedented in the veterinary drug approval process and are beginning to have a negative effect on R&D investments for new animal medicines.

The FDA has proposed the banning of two fluoroquinolone antibiotics for use in the drinking water of poultry due to concerns over microbial resistance development in humans. This key event has caused the animal pharmaceutical industry to further limit R&D spending for new antibiotics in food animals for therapeutic or production purposes.

- David F. Kowalczyk

\* \* \* \* \*

## Program Committee Report

### AAVPT Symposium

The AAVPT Biennial Symposium is scheduled to take place on May 22-24 in Denver Colorado. The social, business, and basic science program sessions will occur on May 22-23 at the Adam's Mark Hotel, just prior to the ACVIM Forum. The clinically oriented program will be given the afternoon of May 23, and the morning of May 24, as part of the ACVIM Forum. Graduate students' research abstract posters or presentations will be included as part of the ACVIM abstract competition. Information on how to submit an abstract can be found at the ACVIM web site at :

<http://www.acvim.org/wwwfp/abstracts/2001abstracts/abstract.htm>

For those persons wishing to attend only the AAVPT/ACVCP portion of the ACVIM Forum, a special one-day registration fee will be offered.

### Basic Science Program

The AAVPT has produced a variety of successful symposia, both biennial and special purpose, to address scientific issues important to veterinary pharmacology. There are important

issues that we are facing, however, that fall outside of the realm of pure science. Such topics that need the profession's attention include the following.

- C Expediting the harmonization of regulatory issues between Europe and the USA.
- C The perceived shortage of qualified candidates to fill veterinary pharmacology vacancies in academia and industry.
- C Bioequivalence and drug availability issues, including Cross-Species extrapolations (as it pertains both to bioequivalence and pharmacokinetic concerns).
- C Establishing a correlation between *in vitro* dissolution data and *in vivo* product bioequivalence.
- C Setting product comparability standards based upon the correlation of kinetic and dynamic relationships.
- C Antimicrobial resistance (from a public health perspective).
- C Unique challenges associated with the development of veterinary controlled release products.

It is for reasons such as these that the Program Committee, with the approval of the Executive Council, has adopted a workshop approach to this part of the program. The proposed format will include presentations explaining a particular problem, followed by a fifteen minute discussion period. After all of the topics have been presented, there will be breakout sessions for each topic to enable participants to explore how the AAVPT might best address the respective issues. These discussions and breakout sessions will culminate in subcommittee reports.

The Program Committee wants to present topics that you will find useful, and those in which you will be willing to participate in the proposed discussions. It is not too late to submit ideas that you would like to see discussed. The AAVPT wants to be a professional organization that **meets your needs**, so please participate! You can contact either myself (Dr. Cory Langston) [langston@cvm.msstate.edu] or the other members of the Program Committee including: Dr. Marilyn Martinez [mmartin1@cvm.fda.gov]; Cyril Clarke [clarke@okstate.edu]; Jane Owens Clark [jane\_o\_clark@groton.pfizer.com]; and Pete Miller [petem@equiaid.com].

### Clinical Program

#### Topics on Antimicrobial Therapy

(Moderator: Dr. Dawn Boothe, Texas A&M University)

- C "Topical/local versus systemic antimicrobial therapy."  
Ted Whittem

- C "Rational use of bacterial culture/ sensitivity data." Mike Apley
- C "Update on the Veterinary Antimicrobial Decision System (VADS)." Cory Langston and Mike Apley
- C "Multiple drug resistance." Cyril Clarke

### **Therapy of Special Patient Groups**

(Moderator: Dr. Cyril Clarke, Oklahoma State University)

- C "Pharmacokinetic implications of kidney failure." Herve Lefebvre
- C "Pharmacotherapeutic implications of hepatic failure." Dawn Boothe
- C "Pharmacotherapy of neonates and pregnant animals." Cory Langston
- C "Pharmacotherapy of immunocompromised animals." Mark Papich

### **Discontinuation of the AAVPT portion of the AVMA Convention Program**

In the last AAVPT Newsletter, the financial concerns regarding the future participation of the AAVPT at the AVMA Convention were explained. In short, speaker expenses were not covered, and the AVMA refused to allow organizations to seek outside sponsorship of programs. These concerns were expressed to the AVMA, but, regrettably, they refused to alter their position. Barring a change in AVMA policy on these issues, the Executive Council has regrettably opted to discontinue the AAVPT portion of the AVMA Convention Program.

- Cory Langston, AAVPT  
(langston@cvm.msstate.edu)

- Cyril Clark, ACVCP  
(clarke@okway.okstate.edu)

\* \* \* \* \*

### **News From Washington**



### **FDA/CVM Proposes to Withdraw Approval of**

### **Fluoroquinolones for Use in Poultry**

In a very significant development in the ongoing controversy concerning regulation of antimicrobial substances used in food animals, CVM is proposing to withdraw approval of the new animal drug application (NADA) for the use of enrofloxacin (fluoroquinolone antimicrobial) in poultry. In accordance with FDA regulations, CVM has issued a notice of opportunity for hearing on its proposal. This notice was published in the October 31, 2000, Federal Register and is also available through the FDA's Dockets Management Branch at: <http://www.fda.gov/OHARMS/Dockets/98fr/cv0076.pdf>. This very significant action is based on CVM's determination that:

1. The use of fluoroquinolones in poultry causes the development of fluoroquinolone-resistant *Campylobacter*, a pathogen in humans, in poultry;
2. This fluoroquinolone-resistant *Campylobacter* is transferred to humans, and represents a significant cause of the development of fluoroquinolone-resistant *Campylobacter* infections in humans, and;
3. Fluoroquinolone-resistant *Campylobacter* infections are a hazard to human health.

The proposal to withdraw the approval for use of enrofloxacin in poultry is based, therefore, on the grounds that new evidence shows the product has not been shown to be safe.

The notice also refers to the approvals of sarafloxacin hydrochloride in poultry. Sarafloxacin water soluble powder was approved for use in control of mortality in growing turkeys and broiler chickens associated with *E. coli* bacteria and sarafloxacin injection was approved for use in controlling early chick mortality associated with *E. coli* organisms in chickens and turkeys. The sponsor of these products has requested withdrawal of the approvals of the NADAs for these products and thus has waived its right to a hearing. Therefore, these NADAs are not included in the notice of opportunity for hearing.

### **Sheep Fully Classified As Species Under FDA Regulations**

Sheep have, for some time, been classified as a minor species with respect to effectiveness and animal safety data requirements. Since data requirements to support NADAs for minor species are significantly less than for major species, such as cattle and swine, the cost of drug development and the time required to complete the process are also significantly reduced.

Heretofore, however, sheep were still classified as a major species with respect to development of data to demonstrate human food safety. Since the development of human food safety data represents a major portion of the cost of development of drugs for food animals, this represented a major deterrent to the

development of drugs for use in sheep.

However, FDA has recently reclassified sheep as a minor species for all data required to support an NADA, including human food safety. Under the reclassification, sponsors of NADAs for drugs for use in sheep may extrapolate human food safety data from cattle to sheep. For example, this rule allows the extrapolation of residue tolerances for drugs approved for use in cattle to sheep.

- Richard H. Teske

Dear AAVPT Colleagues,



This is my last issue as the editor of our "AAVPT Newsletter." Back in 1982, then President Tom Powers asked me, as part of my duties of being President-Elect, to organize and edit a newsletter that would serve in the future to keep

our members fully informed and up to date with regard to AAVPT activities and other matters of interest to the profession on a regular basis. Little did I know then, when I accepted his challenge, that it would become, in reality, what has been truly "a labor of love" for me, one that endured for 19 years.

Things change with time however, and what with advancing computer technology, AAVPT's stated plan for a rapid transition toward greater utilization and reliance upon electronic means of communication whenever possible, the development of a new revised AAVPT web site on the internet, and some additional factors, I believe this is now an appropriate time for me to step aside from the positions I currently hold within the AAVPT, including that of "AAVPT Newsletter" editor. I have elected to do so in order to provide an opportunity for someone new to take over the helm and chart the future course of those areas for which I have been responsible in the past. My decision to begin my new role as an "Emeritus Fellow" was made after considerable thought and careful consideration, and it was personal.

I hope each of you will provide the same fine cooperation and assistance that you gave to me to the individuals who will be appointed to take over my former duties. I have indicated my willingness to be of assistance to them in order to facilitate a smooth transition of these various responsibilities.

Many people assisted me in a wide variety of ways during my tenure as editor, and special mention and words of appreciation go to the following: (1) My former long-time secretary at the University of Pennsylvania, Eleanor Arrington, who helped me type, duplicate, collate, and prepare the mailings, from the very start, during the early years; (2) Dick Teske, who has kept us so very well informed on a continuing basis about news and important new policies originating from the FDA's Center for Veterinary Medicine; (3) Elliott Piperno and, more recently, Dave

Kowalczyk, who faithfully provided updates with regard to developments and new advances made by the pharmaceutical industry, and how they affected both animal and human health issues; (4) AAVPT's past officers and councillors with whom I served, especially the Secretary-Treasurers who established and maintained the computer database that provided me with the mailing labels required for each issue; and finally, (5) The University of Pennsylvania School of Veterinary Medicine for granting me office space following my retirement until now, and for allowing me to utilize their Mail Service, and subsequently reimburse it, for each of the many mailings that it processed on AAVPT's behalf over the past 19 years.

I would also like to express my deep appreciation for the many true and lasting friendships that developed as a direct result of my involvement with the AAVPT over the many years that I was an active Fellow, and for the much appreciated support and encouragement provided by those individuals in more ways than I can ever hope to acknowledge. For all of this, and more, thank you and goodbye!

- Carl E. Aronson

\* \* \* \* \*



## A.A.V.P.T. Newsletter Staff

**Editor:** Carl E. Aronson

### Correspondents

**Industry:** David F. Kowalczyk

**Washington:** Richard H. Teske

**J.V.P.T.:** Jim E. Riviere

**Education:** Gordon L. Coppoc

The **Newsletter** is published three times a year by the **American Academy of Veterinary Pharmacology and Therapeutics**, at the University of Pennsylvania School of Veterinary Medicine. Please address all correspondence to: Dr. Carl E. Aronson, 246 Lynbrooke Road, Springfield, PA 19064-3121 [Telephone and Fax: (610) 544-4262 E-Mail: [aronsonc@vet.upenn.edu](mailto:aronsonc@vet.upenn.edu)].

\* \* \* \* \*



\*\*\*\*\*