



# AAVPT

# Newsletter

**American Academy of  
Veterinary Pharmacology and Therapeutics**

Volume 24, Number 1

September 2005

## FROM THE PRESIDENT

I wish to thank Ted Whittem for his service as President of AAVPT these last two years. During his tenure, he brought us international visibility, streamlined our Bylaws and Constitution and greatly simplified our membership categories. I hope that I can serve this unique organization by following in the ample footsteps of the past presidents, council members and committee chairs. As such, I hope to build on the strong foundation that these capable and dedicated leaders have laid.

For the first time since 1998, AAVPT held a stand-alone scientific meeting as our Biennial Symposium. This event in Rockville MD was a great opportunity for our scientists from academia, industry and regulatory agencies to connect and collaborate on issues and ideas related to our organization's focus: veterinary pharmacology and therapeutics. My sincere hope is that this meeting will serve as a springboard to infuse our organization with a renewed energy and sense of purpose. This symposium was one of our largest to date, in part because of the proximity to Washington, DC, which allowed for many of our US regulatory colleagues to attend and was a convenient city for our international attendees.

### New officers

At the Annual AAVPT business meeting, new officers were announced for the 2005-2007 term. The President is Jane Owens Clark, DVM, PhD, DACVCP; the President-elect is Richard Vulliet, DVM, PhD and the Secretary-Treasurer is Joe Gloyd, DVM. Councilors elected for the 2006 to 2009 term were Cynthia Kollias-Baker, DVM, PhD, DACVCP and Cyril R. Clarke, BVSc, MS, PhD, MRCVS, DACVCP. Anthony Lucas BVMS, PhD also joined the Council as a replacement for a retiring Councillor. AAVPT would like to thank the following officers for their years of service and dedication to the organization: Carol Davis (Secretary-Treasurer 2001-2005), Mark Novtony (Councillor 2003-

2005), Marilyn Martinez (Councillor 2002-2005 and Co-Program Chair for the 14th Biennial), Randy Lynn (Councillor 2002-2005) and Cory Langston (Past-President 2003-2007).

Please see the table in this newsletter for a list of current officers. We urge members to contact these officers with ideas for improving AAVPT. We welcome your feedback.

### Upcoming meetings

AAVPT and ACVCP will jointly sponsor program sessions during the ACVIM Forum in New Orleans, June 2006.

The Fifteenth Biennial Symposium will be held in Asilomar Conference Center, Pacific Grove, CA in May of 2007, which will be our 30th anniversary year. This center is near Monterey, CA and was the venue of the very successful 11th Biennial Symposium in 1998. Like the previous Asilomar meeting, the 2007 symposium will be organized by Rick Vulliet. I fully expect that it will be as fun and eventful as the last one, especially if he again provides two bottles of wine as a welcoming gift!

Owing to the success of the recent 14th Biennial Symposium which was held in Rockville, MD, we will return to this venue every fourth year with the 16th Biennial Symposium to be held in May 2009.

### Future Plans for AAVPT

In keeping with our organization's Mission Statements, the following actions are proposed as areas of focus for the organization over the next two years.

- 1) Mission: Support and promote education and research in veterinary pharmacology and to enhance the exchange of educational materials and ideas among veterinary pharmacologists

Actively recruit Veterinary Pharmacology Educators. Invite them to join and participate in the Education Committee

Fund scholarships for Veterinary Students with interest in Pharmacology. Raise money through corporate sponsorship

Solicit grant money for comparative veterinary pharmacology research. Initially partner with another funding agency

Impact: Increase membership, increase interest in the field of veterinary pharmacology

- 2) Mission: Organize committees of experts to research and make recommendations to the profession on current problems in veterinary therapeutics

Enhance liaisons with AHI, ACVCP, USP, AVMA, Society of Veterinary Hospital Pharmacists, etc.

Reorganize standing committees to be more reflective of current needs in veterinary pharmacology

Minor Use/Minor Species

Pharmacovigilance

Impact: Increase effectiveness of our recommendations pertaining to veterinary pharmacology

- 3) Mission: Sponsor and conduct workshops, symposia or other scientific and educational meetings in veterinary pharmacology and therapeutics.

Hold Biennial in DC every 4 years.

Impact: Increase visibility of Academy, increase membership

Members are encouraged to provide feedback to officers regarding these future plans for AAVPT. Our organization needs your input! We also have opportunities for members to participate in our standing committees. Please contact committee chairs and organization liaisons, if you would like to be join your AAVPT colleagues in service to the organization.

### Current list of Committees:

- Membership and Bylaw's Committee Chair- Ted Whitem
- Membership Committee – Open
- JVPT Editor– Jim Riviere
- Drug Availability and Food Safety –Inactivated at EC Committee Meeting in May, 2005.
- AAVPT Newsletter Committee Chair, Cory Langston
- Awards Committee Chair – Anthony Lucas
- Education Committee Chair – Cory Langston
- Program Committee Chair – Rick Vuillet
- Liaison Responsibilities:
  - USP Information - Cory Langston
  - USP Standards – Mark Papich
  - COBTA – Cory Langston
  - AVMA Animal Agricultural Liaison - Dan Gingerich

**Current officers**

Office	Name	Address	Phone #	Fax	E-mail
President	Jane Owens Clark	Elanco Animal Health 2001 W Main Street Drop Code GL 36 Greenfield, IN 46140	(317) 276-1476	(317) 277-4993	<a href="mailto:clarkjo@lilly.com">clarkjo@lilly.com</a>
President-elect	Richard Vulliet	University of California School of Veterinary Medicine Department of Veterinary Molecular Biosciences Davis, CA 95616	(530) 752-7409	(530) 752-7409	<a href="mailto:rvulliet@ucdavis.edu">rvulliet@ucdavis.edu</a>
Past President	Edward L. B. Whitem	Jurox Pty. Ltd. 85 Gardiners Road Rutherford, NSW 2320,	61 (0)2 4931 8229	61 (0)2 4932 7880	<a href="mailto:tedw@jurox.com.au">tedw@jurox.com.au</a>
Secretary-Treasurer	Joe Gloyd	Gloyd Group 3 Penny Lane Court Wilmington, DE 19803-4023	(302) 761-9690	(302) 761-9680	<a href="mailto:joegloyd@aol.com">joegloyd@aol.com</a>
Councillor 2005-2006	Anthony Lucas	Elanco Animal Health 2001 West Main Street P.O. Box 708 Greenfield, IN 46140	(317) 651 4371	(317) 277 4522	<a href="mailto:lucasan@lilly.com">lucasan@lilly.com</a>
Councillor 2003-2006	Robert P. Hunter	Elanco Animal Health 2001 West Main Street Drop Code GL 36 Greenfield, IN 46140 USA	(317) 655-0958	(317) 277-4993	<a href="mailto:hunterrp@lilly.com">hunterrp@lilly.com</a>
Councillor 2004-2007	Stephen Sundlof	Stephen Sundlof 15032 Wellwood Rd Silver Spring, MD 20905	(301) 384-1264	n/a	<a href="mailto:ssundlof@cvm.fda.gov">ssundlof@cvm.fda.gov</a>
Councillor 2004-2007	Deborah Kochevar	Texas A&M University 4461 TAMU, Dean's Office College of Veterinary Medicine College Station, TX 77843-4461	(979) 845-3878	(979) 845-5088	<a href="mailto:dkochevar@cvm.tamu.edu">dkochevar@cvm.tamu.edu</a>
Councillor 2005-2008	Susan L. Longhofer	Dechra Pharmaceuticals 11 Yeomanry Road Battlefield Enterprise Park Shrewsbury, Shropshire UK SY1 3EH	44 1743 453 076	44 1743 462 120	<a href="mailto:susan.longhofer@dechra.com">susan.longhofer@dechra.com</a>
Councillor 2005-2008	Sanja Modric	Food and Drug Administration FDA-CVM 7500 Standish Place HFV-135 Rockville, MD 20855	301-827-9382	301-827-4317	<a href="mailto:smodric@cvm.fda.gov">smodric@cvm.fda.gov</a>
Councillor Elected for 2006-2009	Cynthia Kollias-Baker	University of Florida 1200 SW 34th St PO Box 100117 Gainesville, FL 32610	530 392-4700 ext 3720	530 846-1052	<a href="mailto:bakerc@mail.vetmed.ufl.edu">bakerc@mail.vetmed.ufl.edu</a>
Councillor Elected for 2006-2009	Cyril R. Clarke	Oklahoma State University Center for Veterinary Health Sciences 205 McElroy Hall Stillwater, OK 74078-0353	(405) 744-8093	(405) 744-6633	<a href="mailto:clarke@okstate.edu">clarke@okstate.edu</a>

## SECRETARY/TREASURERS REPORT

### Membership

Our membership currently stands at 109 Fellows, 17 A. Fellows, 9 Student members, 41 Emeritus, DF, and DE members bringing our base members at about 176 members. This includes active (dues paying members), retired (inactive), Emeritus, Distinguished fellows, DF-emeritus categories.

Here is the breakdown of outstanding dues.

- 1 Has not paid since 2000 (delinquent for 5 years)
- 5 Have not paid since 2001 (delinquent for 4 years)
- 6 Have not paid since 2002 (delinquent for 3 years)
- 35 Have not paid since 2003 (delinquent for 2 years)
- 98 Have not paid since 2004 (delinquent for 1 year)

As of today, we have a total of 98 active members who have paid for 2005 with 35 active members who had paid their dues in 2004 but have not paid for this year. All the members in this category have been sent second notices that their dues are delinquent for 2005. The table above lists each year with the number of members that have not paid their dues since that date. This means we have about 6 members who have not paid since 2002 and an additional 6 how have not paid since 2003. Our policy has been to drop if they have not paid for two years. Therefore, we will lose 6 members (ones from 2002 and 2001). I have noticed a chronic problem in getting all our members to pay their dues in a "timely" fashion. I sent out dues in Jan. and a reminder in April but will still have about 35 members (of 169 active members) who paid in 2004 but have not paid this year. Our core membership (the ones who have paid in 2004 and 2005) currently stands at about 133 members giving us a delinquency rate is at about 21%. This reduces our active membership role by 3 associate fellows, 4 students and 28 fellow members which means about \$1000 in lost dues.

We received award contributions from: Paul E. Adams, Amar N. Bhattacharya, Scott A. Brown, Terrence Clark, Ralph Claxton, Gordon L. Coppoc, John M. Donecker, Marion Ehrich, Daniel A. Gingerich, Joe S. Gloyd, Mitchel H. Greenberg, Ronald L. Highland, William L.

Jenkins, Deborah T. Kochevar, Amy Stuart Neal, Jack W. Oliver, Jane Owens Clark, Mark G. Papich, and Richard Vulliet. We wish to thank all members who have contributed to the awards fund for this year. Total contributions for the year are \$770.00 which brings the award fund up to approximately \$5000.00. We have spent \$500 this past year for the student award which was given at this year's symposium which will bring the award funds to about \$4500.00.

### Election Results

Elections were held in May for 1 President-elect, 1 Secretary-Treasurer, and 2 Counselors. We are pleased to announce that Dr. Richard Vulliet was elected president-elect, Dr. Joe Gloyd was elected Secretary-Treasurer and Dr. Cyril Clarke and Dr. Cindy Kollias-Baker were elected to serve on the council (2006-2009). Dr. Mark Novotny resigned from the counsel effective this year. Dr. Anthony Lucas has been appointed to serve the remainder of his term (one year). The bylaw changes were approved creating a new application procedure and membership category.

### Treasury Report

Income for 2005 was approximately \$7882.00 and total expenses totaled \$7669.27. This does not include the income and expenses for the symposium. A separate report will be prepared for the meeting. I am in the process of closing down the local checking account and moving funds from here to the new treasury account (Joe Gloyd) and the investment accounts (Dan Gingerich). As of July 26, 2005 we have approximately \$17,000 in the local checking account. Outstanding liabilities include \$5,000 to Joe Gloyd to open new account, \$3,100 check for speaker expenses and honoraria, and \$8,000 transferred to our investment accounts. This leaves approximately \$3,000 in the checking account. I will send final check to Dan Gingerich once all outstanding checks and expenses have cleared the bank and will close out the account.

We have had a credit card service since November, 2004. Dan Gingerich arranged for the service in Cincinnati and mailed the terminal to me. We used it to accept dues for 2005 and the registration for the symposium. It works very well and helped immensely with the registration process for the symposium.

## Farewell

This is my last report as I am stepping down as your secretary/treasurer. I wish to thank the membership for electing me to two terms of office and I have enjoyed immensely serving the AAVPT as your secretary/treasurer for the last 4 years. I wish to thank all the AAVPT officers, present and past with whom I have worked. I also want to thank the members of the 14th Biennial Program Committee for all their help this year on an outstanding and successful symposium. I enjoyed working with everyone on the committee on what has been the best attended biennial meeting ever. All the hard work put forth by everyone on the committee paid off and demonstrated perfectly what we can accomplish as an organization. There are no other professional organizations that bring together the three key veterinary disciplines – academic, industrial and regulatory - reflected by our membership and incorporated into our biennial meetings. I wish all the officers the best as they go forward and I particularly wish Dr. Joe Gloyd all the best as he takes over the office this year as your new secretary/treasurer. I hope all of you will help him make a smooth transition.

Submitted July, 2005

Carol A. Davis

Secretary/Treasurer

217-384-2860

[aavptsecretary@insightbb.com](mailto:aavptsecretary@insightbb.com)

### **SECOND NOTICE FOR 2005 DUES**

Announcements were mailed last April. If you have not sent in your 2005 dues please take a few minutes to fill out the dues announcement and mail it along with your check to the secretary. If you did not receive your announcement contact the secretary immediately

## Listserv Is Available To Everyone

The AAVPT listserv is still going. If you have not received any listserv messages in the last couple of months, your email may be wrong in our database. You will need to contact the secretary to have him/her check your email address listing or you can go to our website. You can periodically check you email address by going to our directory on our website and finding your listing in the directory. If it is wrong, click on the

secretary/treasurer hotlink and send an email to request your email address be updated. You can have us add additional email addresses to the listserv if you wish. Please remember – for the listserv to function properly we need to know whenever you have a change in your email address. If you want to change your email listing, you should give us your old email address as well as the new address since it is sometimes difficult match the email addresses to members name. (the mail server just lists the email addresses and does not tell us your name so it is hard to find it in the list unless you provide the email name) We do not have any restrictions on what you can send and there is no screening of messages. We do ask you be considerate to our members and kept the content limited to items that are of general interest to our members.

## How To Use Our Listserv

The procedure for sending messages to our membership is to compose your message and then address the message using the email address for the listserv ([aavpt@listserv.cvm.tamu.edu](mailto:aavpt@listserv.cvm.tamu.edu)). The message will be then be routed through the listserv and to our members. If your email address is on the listserv, the message will be cleared by the server and the message is sent out almost instantly. We do not have any pre-approval procedure for messages. If your email is not on the listserv the message will be stopped and routed to the secretary for approval. If the secretary gets a message from the server, he/she will have to log onto the listserv site and find out why the message was blocked. If it is from one of our members and the email where you are sending the message appears on our listserv, it will be cleared and released for immediate distribution. If the email address is wrong or is not recognized as coming from one of our members, the message will be saved and a message will be sent to the secretary that action needs to taken before it can be distributed. You will know if this happens because you will not receive your copy of the message from the listserv in you inbox. If this is the case, please contact the secretary to clear up the problem. To remind everyone, the listserv will only work if everyone keeps their email current in our database. We encourage everyone to use the listserv and to get some communication going between our members. In addition to members using the listserv, the officers hope to use the system to pass information in a more timely fashion to our members and to get feedback from our members. I remind everyone to periodically go

to the directory and check what email address we have listed for you. To get to your information, go to our website ([www.aavpt.org](http://www.aavpt.org)) and click on "Directory". It will ask you for your user name and password. We use a universal password for all members so you can get into the directory by entering "aavpt" for the user name and "acadmem" for the password. (In both cases, do not type the parentheses) You can then type in your name and it will list your directory information. Check the information we have for you and report any errors or changes by clicking on the "secretary-treasurer" hot link so it can be corrected it in our membership database and entered into the listserv database.

## MEMBERSHIP AND BYLAW'S COMMITTEE

At the AAVPT Annual General Meeting in Washington DC in May, the academy approved several changes to its constitution. The new constitution is now available for your review on our website at [www.aavpt.org](http://www.aavpt.org). The following is a summary of the main effects of the changes.

- We updated the name and purpose of the Journal to reflect changes already made at the Executive level in agreement with the international sister organizations. The Journal is now to include clinical toxicology (see Jim Riviere's news item?).
- We changed the name of the type of membership formerly called "Associate Fellow" to "Member" (and associated change to the name of Emeritus Associate Fellows to Emeritus Member).
- The process for gaining each type of membership was changed to ease process for gaining Membership. We also changed the requirements for obtaining membership within the different categories as follows (in brief)
- Membership is now available to any university graduate with a demonstrated interest in veterinary pharmacology and who wishes to join, without further restriction
- Fellowship can be granted only to Members who have varying years of experience in the

discipline, depending upon their academic qualifications.

- Student membership is restricted to a maximum of 6 years.

The Constitution and Bylaws Committee is next to reconsider other aspects of our structure. In particular, I am interest in receiving input from Members and Fellows on their attitude to council membership and office holding. Currently, these opportunities are restricted only to Fellows. Should we not also include Members on our council and allow them to hold office?

## PROGRAM COMMITTEE REPORT

*Jane Owens Clark*

The 14th Biennial Symposium, entitled 'Veterinary Pharmacology 2005: Advances, Challenges, and Insights' was held from May 16 – May 18, 200 at the Doubletree Hotel in Rockville, MD. This symposium turned out to be one of our most ambitious meetings to date with 100 registrants, 31 speakers and 15 corporate sponsors. Participants came from countries around the globe including France, Israel, Great Britain, France, Argentina, Australia, New Zealand and the United States.

In keeping with our organization's tripartite mission, the meeting focused on three themes – Regulatory, Science, and Teaching. The program was divided into morning plenary sessions, followed by concurrent afternoon breakout sessions, which in total offered twenty-four hours of continuing education in veterinary pharmacology. Plenary speakers included Dr. Lester Crawford, who was recently named as Commissioner of the FDA; Dr. Stephen Sundlof, Director, Center of Veterinary Medicine, FDA; Dr. Pierre-Louis Toutain, Professor, Ecole Nationale Vétérinaire de Toulouse; Dr. Steven Vaughn, Director, Office of New Animal Drug Evaluation, CVM/FDA; Dr. Quintin McKellar, Principal and Dean, Royal London Veterinary College; Dr. Gatz Riddell, Auburn University, Chair of the AVMA's Council on Biologic and Therapeutic Agents; Dr. Jim Riviere, Professor, College of Veterinary Medicine, North Carolina State University; and Dr. Stefan Soback, Kimron Veterinary Institute, Ministry of Agriculture, Israel.

Program topics included: the role of pharmacokinetics and pharmacodynamics in the development and regulation of new veterinary drugs, developments in teaching veterinary pharmacology, integrating scientific advancements into drug regulation, veterinary allometry, and a special session on veterinary compounding. A continuing education short course was held on the last day of the conference entitled 'Good laboratory practices: Successfully managing a GLP facility'.

A complete set of the proceedings of this meeting is available at the International Veterinary Information Service (IVIS) website, <http://www.ivis.org/aavpt>. A synopsis of the presentations provided during the meeting will also be published in an upcoming article in JVPT.

Our generous sponsors submitted over \$20,000 in funding which allowed us to offer honoraria to our many speakers and to enjoy special features such as the classical music trio which entertained attendees at the social hour, poster viewing and banquet. Other special events included a graduate student lunch, oral presentation of selected posters and vendor presentations. The committee would like to thank Applied Biosystems, Monsanto, ELANCO, Avogadro, Bayer Animal Health, Exygen Research, Intervet, Inc, Merial Limited, Pfizer Animal Health, Vetoquinol S.A., Advion BioServices, Inc, IDEXX Laboratories, Inc, Microbiological Business Consultancy, Schering-Plough Corporation, and Virbac Corporation for their generous sponsorship of the 14th Biennial Symposium. Further, thanks to the Program Committee Members for their hard work and months of planning in making this symposium a success: Marilyn Martinez, Jane Owens Clark, Pierre-Louis Toutain, Carol Davis, Cory Langston, Rob Hunter, Bernadette Dunham, Guilin Qiao, Julia Punderson, Anthony Lucas, and Ted Whitem.

## **JOURNAL OF VETERINARY PHARMACOLOGY AND THERAPEUTICS (JVPT)**

*Jim Riviere*

Journal of Veterinary Pharmacology and Therapeutics: This has been a great year for JVPT! Its Impact Factor has increased to 1.23, a 35% increase from last year and the highest it has ever been! This ranks JVPT in the top

20% of all veterinary journals. Manuscript submission remains strong. Please remember that toxicology of therapeutic agents is now within the purview of the journal. Please send us your veterinary toxicology papers dealing with the toxicity of drugs and chemicals used in veterinary species. Dr. Mark Papich is now the review editor replacing Dr. Jonathan Elliott. Should you have ideas for review articles, please contact Mark. I also would like to thank the efforts of Drs. Duncan Ferguson and Steve Sundlof whom are rotating off the Editorial Board. They have done an outstanding job of keeping up the quality of articles which is reflected in the impact factor. Drs. Lauren Trepanier and Michael Apley will be joining the Board. Also, Dr. Peter Lees is stepping down as the long time co-editor of JVPT. His replacement has not been identified as of the date of this report. Finally, we are making progress on the "webification" of JVPT so that all submissions and reviews are done completely on-line. This was slightly delayed due to the pending resignation of Peter as the new European Editor must be involved in implementing these changes. Thank you again for giving me the honor of serving AAVPT as the journal's editor.

## **AWARDS COMMITTEE**

*Anthony N Lucas*

Several awards were presented during the 14th Biennial Symposium at the Doubletree Hotel in Rockville, MD on May 16 – May 18, 2005. The Lloyd E. Davis Award for significant contributions to the advancement and extension of knowledge in veterinary or comparative pharmacology was presented to Dr. Desmond Baggott. Dr. Baggott has made significant contributions to veterinary pharmacology in no less than ten schools across the globe, which included the founding of several pharmacology programs. He is currently serving as Professor of Veterinary Pharmacology and Toxicology and Associate Dean of Clinical Training at the School of Veterinary Medicine, St. George's University, Grenada, West Indies. Dr. Baggott was also given the honor of Distinguished Fellow for his outstanding contributions in veterinary pharmacology.

Also honored at the symposium was Dr. Lester Crawford, Commissioner of the U.S. Food and Drug Administration (FDA), who is the first veterinarian to be named as head of the nation's drug regulatory agency. He was given the honor of Distinguished Fellow for his

years of service in both veterinary and human pharmacology.

The AAVPT/ACVCP Resident Graduate Student Award was presented to Dr. Mathieu Peyrou (Faculte de Medecine Veterinaire, University de Montreal, Quebec, Canada). The purpose of the Award is to recognize research excellence in clinical and/or basic pharmacology for residents and graduate students. Dr. Peyrou's poster was entitled "Enrofloxacin and marbofloxacin in horses: comparison of pharmacokinetic parameters and use of urinary data to estimate first-pass effect and absorbed fraction". Dr. Peyrou's mentor was Dr. Michèle Doucet, a diplomate of both the American College of Veterinary Internal Medicine and the American College of Veterinary Clinical Pharmacology from the Department de Biomedecine Veterinaire, Faculte de Medecine Veterinaire, University de Montreal, Quebec, Canada.

## LIAISON REPORTS

### USP Drug Information

*Cory Langston*

The USP held its quinquennial convention to begin its 2005-2010 cycle. Trish Dowling was elected Chair of the Veterinary Drug Information Expert Committee to replace Cory Langston who stepped down after chairing two cycles. Mark Papich continues as the Chair of the Veterinary Drug Standards Expert Committee.

A drug information monograph series on dewormers (macrocyclic lactones and tetrahydropyrimidines) is in its final revision following a public comment period and should be available soon for publication. It will join the series on antimicrobials and anti-inflammatories already published in JVPT and available at no charge at [www.usp.org](http://www.usp.org).

A joint effort between the USP Veterinary Information Expert Committee, Veterinary Standards Expert Committee, and the USP Compounding Pharmacy Committee is underway to supply needed information on compounded veterinary products. Initial efforts are directed towards bromide. Already a drug standard monograph for potassium and sodium bromide has been published in the Pharmacopoeial Forum volume 31(2)

2005. A drug information monograph on proper use of the drug has gone through public review and publication is pending. Work on a third monograph by the Compounding Pharmacy Committee regarding formulation stability is pending. Other compounded drugs being considered for monograph creation include: metronidazole and metronidazole benzoate, methimazole, DES, PPA, amitriptyline, piroxicam, and prednisolone.

### AVMA COBTA

*Cory Langston*

Dawn Boothe completed her term on COBTA this July. During her term Dawn served key roles including Chair of COBTA and CPAC and was pivotal to many of the decisions reached by COBTA. Don Sawyer was elected to fill Dawn's position in the discipline of pharmacology. Cory Langston continues in his 2<sup>nd</sup> year representing clinical pharmacology on the committee.

The FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance held in Geneva, Switzerland in December 2003 (Scientific Assessment) and in Oslo, Norway in March 2004 (Management Options) recommended that the OIE should develop a list of critically important antimicrobials in veterinary medicine. This list would identify those antimicrobials for treatment, prevention and control of serious animal infections that may have important consequences for animal health and welfare, public health or important economical consequences and where there are few or no alternatives. The list is intended to safeguard the efficacy and availability of veterinary antimicrobial products for diseases where there are few or no antimicrobial alternatives. The list could help veterinarians in their therapeutic choice and could be useful for the risk assessment of antimicrobial resistance.

### **The following were recommendations by COBTA that were subsequently approved by the AVMA Executive Board to represent AVMA policy or positions:**

- Regulatory jurisdictional issues were raised relative to a manufacturer with a biologic for cattle intended to reduce shedding of *E. coli* O157:H7. On initial examination the USDA had declined to review the license application suggesting that it instead should

go to the FDA. The Council approved a motion to recommend that the USDA APHIS assume jurisdiction for the regulation of animal biologics that impact food safety. Subsequently, in response to multiple requests, the APHIS and FDA have agreed that the jurisdiction for animal vaccines targeted at the reduction or elimination of a carrier state of organisms that can infect other animals (even if that infection is only rarely associated with significant clinical disease in animals) will lie with APHIS as long as certain criteria are met. (see

<http://www.aphis.usda.gov/vs/cvb/notices/2005/07.pdf#search=reduction%20or%20elimination%20of%20a%20carrier%20state>)

- The Council recommended that a Veterinary Biologics Advisory Committee be created within the USDA. COBTA believes the committee should be created to provide advice and counsel to the USDA about issues important to the veterinary profession concerning the licensing and use of veterinary biologics.
- Off-label use of pesticides is strictly prohibited by the EPA. The Council noted that ectoparasite treatment in minor species such as pet reptiles, pocket pets, rabbits, ferrets, pet birds, camelids and captive wildlife can create a conundrum for veterinarians because no EPA-registered pesticides are labeled for use in these species. COBTA recommended that the EPA extend regulatory discretion to licensed veterinarians who use their professional judgment, within a veterinarian-client-patient relationship, to use EPA-registered pesticides in an off-label manner to ensure animal and human health when no EPA-registered pesticide is clinically effective as labeled.
- Concerns had been expressed by the AAEP regarding the sale of equine blood products (plasma) of dubious quality that have resulted in adverse reactions. The USDA Center for Veterinary Biologics regulates the quality of equine blood products that bear immunologic treatment or disease label

claims; however, equine blood products that bear no particular treatment or disease claim on labeling are produced without any active federal regulation of product quality. The AVMA urged the FDA / USDA to assume regulatory control to assure the quality of equine blood products. The FDA and USDA APHIS have in return asked that they be notified of any specific quality issues or advertisement of non-licensed products for therapeutic purposes.

- COBTA approved a motion that the AVMA send a letter to the FDA Center for Veterinary Medicine expressing concerns identifying salient epidemiological points relative to how the agency reviews and interprets adverse event reports. Assistance to the FDA from expert AVMA members was offered.
- COBTA recommended to the DEA that the new prescription drug Tributame, an embutramide-containing injectable euthanasia solution (see News section), should not be placed into a controlled drug status. AVMA feels that “the characteristics of the final formulation vitiate the potential for abuse and the benefits of an unscheduled humane euthanasia solution are exceedingly valuable.”

## American College of Veterinary Clinical Pharmacology

*Terry Clark*

The American College of Veterinary Clinical Pharmacology (ACVCP) met in conjunction with the AAVPT Biennial Symposium. At the ACVCP business meeting, new officers were announced for the 2005-2007 term. The President is Debbie Kochevar, DVM, PhD, DACVCP (Texas A&M University, College Station, TX); President-elect, Mike Apley, DVM, PhD, DACVCP (Kansas State University, Manhattan, KS); Vice President, Michèle Doucet, DVM, PhD, DACVCP (Faculté de médecine vétérinaire, Saint-Hyacinthe, Québec, Canada); and Secretary-Treasurer, Albert Boeckh, DVM, PhD, DACVCP (Merial Limited, Duluth, GA).

## SCIENTIFIC POINTS OF INTEREST

### **“Why MRLS was never previously identified?” or “Caterpillars abort mares following strict mathematical principles!”**

**Thomas Tobin, MVB, MSc, PhD, DABT (Gluck Center)**

A basic question about the Mare Reproductive Loss Syndrome (MRLS) is why it was never identified prior to 2001. A recent mathematical analysis has provided an unusual but very convincing answer to this question. It turns out that caterpillars abort mares following strict mathematical principles. Exposure to caterpillars is followed by a dose-dependent “lag” time, after which the abortions start, and the rate at which the abortions occur depends strictly on the dose of (read numbers of) caterpillars.

If the dose (exposure) of caterpillars is low, the “lag time” is quite long, and most abortions occur after the caterpillars are gone. This is what happens in most years, and is the reason that MRLS was never previously identified. On the other hand, when exposure to the caterpillars is very high, as in 01, the lag-time is very short. Abortions can begin at 30 hours post-exposure to caterpillars, while the caterpillars are underfoot and very obvious. In 01 this led to time and place associations between the caterpillars and the abortions, which pointed to the caterpillars as the cause of MRLS. The mathematical analysis used is called Accelerated Failure Time analysis, and this analysis has never previously been applied in equine toxicology.

Dr. Tobin can be reached by email for more information at [ttobin@uky.edu](mailto:ttobin@uky.edu). or see Vet. Therapeutics, Vol 4 #4 P 324, Winter 2003. An additional article on the topic may be found at <http://www.jarvm.com/articles/Vol2Iss2/TOBINJARVMVol2No2.pdf>.

## NEWS

### **Food and Drug Administration**

**CVM revises industry guidance document on safety evaluation of compounds for food-animals**

The Center for Veterinary Medicine in June issued a revised industry guidance document, “General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals,” that updates the section on toxicological testing of substances used to treat food animals and fixes minor errors in the document it replaces.

The Federal Food, Drug, and Cosmetic Act requires the Food and Drug Administration to determine whether food additives, new animal drugs, or color additives that sponsors propose to use in food-producing animals are safe. To do that, FDA requires sponsors to furnish scientific data demonstrating that the residue of any product used in a food-producing animal is safe for humans who consume food from that animal.

The guidance document, which is Guidance for Industry #3, describes for sponsors the kinds of data that FDA believes will provide an adequate basis to determine whether a compound is safe.

Many of the changes from the earlier version are in section two, “Guidance for Toxicological Testing.” This section refers to other guidance documents accepted by FDA and CVM that were originally developed under the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). VICH includes the European Union, Japan, and the United States. It is a program aimed at harmonizing technical requirements for veterinary product registration in all three areas. The VICH guidance documents are included by reference.

The revised guidance document #3 includes a reference to a guidance drafted by VICH describing a general approach for establishing a microbiological ADI, which the earlier guidance document did not have.

The guidance document contains seven sections. Sections one and four describe appropriate scientific studies for obtaining information on probable consumption of the sponsor’s compound and its residue. Sections two and three describe the appropriate scientific studies for obtaining information on the toxicity of the compound and its residues, and explain the safety factors used. Section six describes the appropriate studies for showing the safety of “biomass” products. And section seven describes the studies needed to perform the risk

assessment on bound residues of carcinogenic veterinary drugs.

Guidances such as this one do not establish enforceable responsibilities. Instead, they describe the Agency's current thinking.

The guidance is available on CVM's website ([www.fda.gov/cvm](http://www.fda.gov/cvm)), under "Guidances."

### **FDA Commissioner orders withdrawal of approval for enrofloxacin in poultry**

U.S. Food and Drug Administration Commissioner Lester Crawford announced the Agency's final decision in late July to no longer allow distribution or use of the antimicrobial drug enrofloxacin for the purpose of treating bacterial infections in poultry.

The enrofloxacin is a fluoroquinolone and has been marketed under the name Baytril® 3.23% Concentrate Antimicrobial Solution by Bayer Corporation.

The Center for Veterinary Medicine began proceedings to withdraw use of the drug in poultry because scientific data showed that the use of enrofloxacin in poultry caused resistance to emerge in *Campylobacter*, a human pathogen. These resistant bacteria multiply in the digestive tracts of poultry, and are found on chicken carcasses in slaughter plants and on retail poultry meats.

The Administrative Law Judge who initially reviewed the case and the Commissioner, after reviewing all the documents and testimony submitted in evidence during the hearing process concerning the proposed withdrawal of approval, concluded that CVM had showed that:

Enrofloxacin use in poultry acts as a selection pressure, resulting in the emergence and dissemination of fluoroquinolone-resistant *Campylobacter* species in poultry;

Fluoroquinolone-resistant *Campylobacter* species in poultry are transferred to humans and contribute to fluoroquinolone-resistant *Campylobacter* infections in humans; and

Fluoroquinolone-resistant *Campylobacter* infections in humans have the potential to adversely affect human health; therefore,

The use of enrofloxacin under the approved conditions of use in poultry has not been shown to be safe.

This ruling does not affect other approved uses of the drug. The final rule withdrawing approval of the drug will be effective on September 12, 2005. For the final decision is available at [www.fda.gov/oc/antimicrobial/baytril.pdf](http://www.fda.gov/oc/antimicrobial/baytril.pdf). Federal Register documents are available at [www.fda.gov/ohrms/dockets](http://www.fda.gov/ohrms/dockets).

Editor's note: On September 2 Commissioner Crawford denied a petition for a stay of action on the effective date of removal of Baytril approval in poultry.

### **Dr. Lester M. Crawford Appointed Commissioner of the FDA**

On July 18, 2005, the Senate approved the nomination of one of AAVPT's Distinguished Fellows, Dr. Lester Crawford, to be Commissioner of the Food and Drug Administration (FDA). Dr. Crawford is a dedicated public servant who has ably led the agency over the last year and previously served as Deputy Commissioner. As Commissioner of the FDA, the nation's principal consumer protection agency, Dr. Crawford ensures the safety and protection of the public's health.



Previously, Dr. Crawford was Chair of the Department of Physiology-Pharmacology at the University of Georgia, Administrator of the Food Safety and Inspection Service (USDA) and Deputy Commissioner of FDA. From 1997-2002, he was Director of the Center for Food and Nutrition Policy at Georgetown University and at Virginia Tech, where it moved in 2001.

Dr. Crawford has played major roles in mandatory nutrition labeling, the formation of the World Trade Organization and the control of chemical and microbiological contaminants of food. He has been

an advisor to the World Health Organization of the United Nations for much of his career.

Dr. Crawford is a Member of the National Academy of Sciences Institute of Medicine. He is a Fellow of the Royal Society of Medicine (UK) and a Fellow of the International Society of Food Science and Technology. In 1984, he was inducted into the French Academy of Veterinary Medicine. In 1991, he received the Wooldridge Award, the British Veterinary Association's highest award.

Dr. Crawford received his Doctor of Veterinary Medicine (DVM) from Auburn University, his PhD in pharmacology from the University of Georgia, and his Honorary Doctorate (MDV) from Budapest University.

He has been married since 1963 to Catherine Walker of Birmingham, Alabama. They have two daughters, Leigh and Mary, and four grandchildren. Source: <http://www.hhs.gov/news>.

### **Linda R. Tollefson is Appointed as FDA's New Assistant Commissioner for Science**

U.S. Food and Drug Administration (FDA) Commissioner Dr. Lester M. Crawford announced today the appointment of Rear Admiral Linda R. Tollefson to the position of Assistant Commissioner for Science. Most recently, RADM Tollefson served as Deputy Director of the Center for Veterinary Medicine (CVM). In her new position, she will also serve as Coordinator for Commissioned Corps Affairs at FDA and direct FDA's Offices of Women's Health and Orphan Products Development.

### **Tulathromycin single-dose full therapy injectable for bovine and swine respiratory disease**

DRAXXIN (tulathromycin) by Pfizer Animal Health is the first of a new macrolide subclass of antimicrobials called the triamilides. It is indicated as a single-dose full course therapy for treatment and control of respiratory disease in cattle and swine. Draxxin is also the first animal antimicrobial to receive approval under the new

Guidance 152 review process with respect to the potential for transfer of antimicrobial resistant organisms to humans.

### **Pyrimethamine + sulfadiazine approved for EPM**

REBALANCE is an oral suspension of sulfadiazine and pyrimethamine by Animal Health Pharmaceuticals for veterinary prescription use for the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*.

### **Meloxicam for dogs and cats**

METACAM (meloxicam) by Boehringer Ingelheim Vetmedica is an NSAID available in an oral suspension and an injectable formulation for control of arthritis pain in dogs. The injectable formulation is also approved in cats for single-dose preoperative use to decrease post-surgical pain.

### **Ceftiofur intramammary infusion**

SPECTRAMAST LC (ceftiofur hydrochloride) by Pharmacia & Upjohn provides for the veterinary prescription use of ceftiofur hydrochloride suspension, by intramammary infusion, for the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*.

### **Embutramide euthanasia solution**

TRIBUTAME by Phoenix Scientific is a euthanasia solution approved in dogs containing embutramide, chloroquine, and lidocaine. (Embutramide was an ingredient in T61, a euthanasia product previously used in the USA but no longer available.) The DEA has proposed that the formulation be considered a class III controlled substance as embutramide can be hydrolyzed to derive gamma-hydroxybutyric acid (GHB), a date rape drug. (See COBTA liaison report for AVMA letter to DEA regarding this subject.)

## POSITIONS AVAILABLE

### Jurox

Jurox is a 100% Australian owned company operating in the Animal Health and Rural Industries. We seek a veterinarian with both interest and experience in small animal therapeutics. The new position includes an initial 3 year training position structured to complete credential requirements for candidates for Fellowship of the Australian College of Veterinary Scientists or for Diplomate certification by the American College of Veterinary Clinical Pharmacology. This program includes training in basic pharmacology and therapeutics, formulation science, analytical chemistry, experimental design, statistics, GxP, management of adverse events and in regulatory veterinary medicine. Access to formal course-work training in pharmacology is available. The position is a permanent position, located in our Rutherford facility in the Hunter Valley of NSW. Applications which include copies of the candidate's academic record, curriculum vita, statement of career goals and which nominate two referees should be sent to: Dr. Ted Whitem, Head of R&D, Jurox Pty Ltd, 85 Gardiners Road, Rutherford NSW 2320 prior to 15 September 05, or to [jenq@jurox.com.au](mailto:jenq@jurox.com.au)

### Pfizer

Pfizer seeks a Principal Scientist to support the discovery of new drugs for companion animals including dogs, cats and horses. The individual will be responsible for the design and conduct of studies to evaluate potential new veterinary medicines. The individual will be expected to independently evaluate appropriate medical literature, create clinical assessment tools, identify and acquire appropriate technology and design and implement clinically relevant models to assess the efficacy of analgesic medications. The successful candidate will also participate in and coordinate studies conducted by outside collaborators or in collaboration with academic institutions. The individual will lead and/or participate in multi-disciplinary teams and will be expected to supervise one or more scientists. Requirements include a DVM with a minimum of two years experience in the clinical evaluation and treatment of pain associated with disease or trauma in cats, dogs and possibly horses is required. Experience with the use and assessment of analgesics and anesthetics would be advantageous. A PhD in related discipline with

emergency medicine, internal medicine or veterinary pharmacology is desirable. Additional desirable experience includes prior experience in drug discovery or development within the pharmaceutical industry. Applications must include a letter indicating special qualifications and scope of experience and curriculum vita. If interested, please visit our website at [Pfizer.com](http://Pfizer.com) to apply for posting Job#: 038432.

### Idexx

IDEXX is looking for a few veterinarians to work in the pharmaceutical and diagnostic groups.

For information contact:

Randy C. Lynn, DVM, MS, DACVCP  
Director, Professional Services Group  
IDEXX Pharmaceuticals, Inc.  
tel: 336-834-6506; cell: 336-456-6312  
fax: 336-834-6525  
[Randy.Lynn@idexxpharma.com](mailto:Randy.Lynn@idexxpharma.com)

### Elanco

Elanco Animal Health, a division of Eli Lilly and Company, located in Greenfield, IN, is recruiting a Research Scientist who will be responsible for assessing the absorption, distribution, metabolism and excretion (ADME) of pharmaceuticals being developed or marketed for companion animals or livestock. As part of a multidisciplinary team, the successful candidate will lead the design and implementation of pharmacokinetic, metabolism and residue programs to support product development and registration commitments of veterinary pharmaceuticals. The candidate will also serve the Study Director/Sponsor Representative for ADME studies, critically review all relevant ADME data, and author or review GLP and non-GLP study reports. In addition they may supervise laboratory associates in the generation and evaluation of data as well as develop and validate methods used for the quantitation of drug and/or metabolites in complex biological matrices. Job requirements include a PhD or equivalent in pharmacology, biochemistry, analytical/bioanalytical chemistry or related field or equivalent experience. Experience in bioanalytical determinations utilizing sample preparation techniques and HPLC/MS is also required. To apply go to [www.lilly.com](http://www.lilly.com); Job Search ID: 50220707

## OBITUARY

Dr. William G. Huber (DVM IL 52, MS 57, PhD 60), of Sun City West, Ariz., died April 20, 2005. He was a member of the University of Illinois College of Veterinary Medicine's first graduating class and later spent 13 years as a faculty member at UI, eventually leaving to become director of research for the international pharmaceutical company Hoffman La Roche. In 1997, he and his wife established the Dr. William G. and Joyce F. Huber Veterinary Medicine Library Endowment Fund to honor his classmates, two former deans of the college, Dr. Robert Graham and Dr. Carl A. Bradley, and a former professor, Dr. Roger P. Link. Funds from the Huber Endowment are used to purchase books for the veterinary medicine library. When the endowment was created, he remarked: "The library is an integral part of the veterinary medicine program. The better the library, the better the program." Memorials may be made to this endowment.



### AAVPT Newsletter Staff

Editor: Cory Langston

The Newsletter is published twice yearly by the American Academy of Veterinary Pharmacology and Therapeutics. Please kindly address all correspondence to:

Dr. Cory Langston  
College of Veterinary Medicine  
PO Box 6100  
Miss. State, MS 39762-6100  
USA  
email: langston@cvm.msstate.edu.