FROM THE PRESIDENT

Carol A. Davis

Well, welcome to the spring issue of the newsletter. We, in central Illinois, are beginning to see some signs of spring. I am glad to see warmer days and things beginning to “green up” and the early spring flowers popping up all around my neighborhood. This kind of weather always helps to improve my attitude and makes me think about golf. My clubs are calling! Hopefully, I will get some practice rounds in before my league starts in May. It has been a very busy year for all of us in AAVPT. The newsletter contains reports on the work being done in the various committees and the programs we have been developing and offering over the last year.

Sanja’s report will go into the programs she has been working on, but I would like to report on the collaboration we have with the American Association of Pharmaceutical Scientists (AAPS). In November of last year, the AAVPT and ACVCP co-sponsored a workshop with the AAPS which was presented at the 2010 AAPS Annual Meeting and Exposition/International Pharmaceutical Federation’s Pharmaceutical World Congress in New Orleans. The workshop, Contemporary Challenges and Advances Impacting the Development of Veterinary Pharmaceuticals, brought together pharmaceutical and veterinary scientists from industry, academia and government agencies to discuss current drug development challenges. This was the third workshop we have co-sponsored with AAPS and the first time we had participation from ACVCP. Topics covered in the workshop included global regulations under the Veterinary International Conference on Harmonization (VICH) and the challenges of such harmonization to the animal health industry; emerging tools in veterinary medicine (e.g., pharmacogenomics, population PK and biomarkers); discussion of the some of the major impediments to bringing truly novel animal drugs to the market, and others. One of the more intriguing topics at the workshop was presented by Dr. David Vail from the University of Wisconsin-Madison. Dr. Vail is the director of the Center for Clinical Trials and Research at the School of Veterinary Medicine and spoke about the development of the Canine Comparative Oncology and Genomics Consortium (CCOGC). He discussed the use of the “species in kind” approach to preclinical and clinical investigations in spontaneously occurring tumors in dogs and how this technique might be used to characterize and predict clinical performance of oncology products for human health product development. It is a good example of how naturally occurring diseases in animals can be used for drug development. We appreciate the support we have received from AAPS and...

CONTINUED ON PAGE 2

ANNOUNCEMENTS

- AAVPT 17TH BIENNIAL SYMPOSIUM MAY 22-25, 2011 UNIVERSITY OF WISCONSIN-MADISON LOWELL CENTER CONFERENCE AND LODGING FACILITY (SEE PAGE 5)
- DUES, SUBSCRIPTIONS & CONTRIBUTIONS CAN BE PAID ONLINE AT WWW.AAVPT.ORG
- BALLOTS DUE MAY 9 BY 5 PM
- SPECIAL BOOK SAVINGS FOR AAVPT MEMBERS (SEE PAGE 4)
FROM THE PRESIDENT (CONTINUED)

the AAPS program committee over
the years for our workshops. We
hope we will have another collabora-
tive workshop with them in the fu-
ture.

Our biggest project this year was
the VDRLC course presented in
March 2011. It, by far, was the
most ambitious program we have
ever undertaken. It ran a full week
and included over 60 speakers. It
also included a first for AAVPT--it
was the first meeting we ran using
on-line registration. The particular
on-line service we used had its
quirks and gave some of us some
worries; in the end, it worked out
and did help us handle the regis-
tration fees. We could not have
pulled the meeting off without
it. Again, the Bolger Conference
Center provided excellent facilities
and meals for the entire week, and
I believe the response to the meet-
ing was good.

I want to take this opportunity to
tank everyone who worked on
the VDRLC course. Special thanks
go out to Dr. Bernadette Dunham
and the management and staff
at CVM for their hard work and
allowing us to present the course.
And then I have to again thank
Anthony, Ralph, Sanja and Michele
for their help. It truly was a great
experience working with them,
and although I am very happy to
have the meeting completed, I miss
our weekly get-togethers! I know
I have said this many times in the
past, but it so true--these meetings
take a tremendous amount of time
and effort to plan and carry out. I
hope everyone involved knows I
truly appreciate all of their effort.

Although it has been a busy year
with these programs, we have
continued to work on our 2011
Biennial Symposium. I am looking
forward to the meeting in Madi-
son. We have some great events
planned for the meeting including
a fish fry to kick off the meeting
on Sunday. We were a little late in
getting our on-line service up and
running for the registration, but it
is now open. I encourage everyone
to register as soon as you can, so
we can begin to make final plans
for the meeting. I always enjoy
this meeting and look forward to
visiting with everyone.

Related to other activities in
AAVPT, we are beginning to turn
our focus on working on one
of the goals we set in motion at
the beginning of my tenure as
president--streamlining the op-
eration of the academy by using
web-based services. We learned a
lot about on-line registration with
our VDRLC course and are now
implementing on-line payment
dues and registration for our
symposium with another company
called Affiniscape, Inc. It is a web-
based association management
software service which we should
be able use to deliver meeting
registrations and to manage our
membership database. It serves
small non-profit professional
groups like AAVPT. They have
modules which can be added to
help improve the various aspects
of membership services. Obvi-
ously, there are recurring fees with
this service, but we were at a point
where we needed to do something
to help reduce the workload of our
elected officers. We are currently
using it to handle our dues for
2011 and registration for the sym-
posium. Although the service we
have right now is limited to on-line
payments only, we will expand it to
handle our membership database.
This will allow us to better track
our membership and keep our
accounts more up-to-date. More
information will be provided as we
get more features added.

Our standing committees are
also working on several projects.
We continue to work on the
monographs and finding ways
utilize them. Ronette Gehring
is working with her commit-
tee on how to do this and is in
discussions with ACVCP on how
we might work together to keep
the monographs current. Cory
Langston has been working on
getting an on-line pharmacology
test database. Both these tasks
will take considerable effort, but
we look forward to seeing more
information as they move forward.

I hope to see you at the Biennial.
FROM THE PRESIDENT-ELECT

Sanja Modric

Most of my work in the past six months has revolved around the two big meetings that we were putting together for this year: the AAVPT Veterinary Drug Regulatory Life Cycle Course and the 17th Biennial Symposium. As a result, my president-elect report will consist primarily of updating you on those activities.

As we are getting ready for the next Biennial Symposium in May of this year and the upcoming business meeting, I would like to thank everybody who provided nominations and/or volunteered for the open positions that we have on the Executive Council. The ballots were sent out, and the new officers, including the new president-elect and secretary/treasurer, will be announced at the Biennial Symposium.

AAVPT Veterinary Drug Regulatory Life Cycle (A to Z)

It is hard to believe that Anthony’s dream of providing the veterinary pharmaceutical industry with a training program similar to the USDA’s Veterinary Biologics Course has finally come to fruition! It’s been about nine months since the program committee (Ralph Claxton, Carol Davis, Anthony Lucas, Michele Sharkey and I) approached CVM’s director, Bernadette Dunham, to propose such a course, and we are happy to report that the Life Cycle Course was successfully completed on March 4, 2011. It was a week-long course organized and sponsored by the AAVPT and was held at the Bolger Conference Center in Potomac, Maryland. All the course materials were presented by the FDA Center for Veterinary Medicine, with a total of 62 speakers (representing a mix of subject-matter experts and managers). The course provided a comprehensive overview of the veterinary drug life cycle from the drug’s early development to its life on the pharmacy shelf and beyond.

Because the program committee wanted to assure open communication and networking at the meeting, attendance was limited to 100 participants (from industry, research organizations, academia, and regulatory agencies). CVM employees who could not attend the workshop in person were able to watch the entire workshop from their offices via WebEx live streaming. In addition, the workshop was recorded and is available from the CVM website (http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm249768.htm). Workshop videos are broken down into individual searchable presentations grouped by subject areas.

The goals of the workshop included:
- Educating CVM’s partners (industry, clinicians, researchers) and employees about the veterinary drug approval process and the complete life cycle of veterinary drugs
- Improving submission quality by providing the scientific and regulatory justification for veterinary drug approval process requirements
- Creating a non-stressful, open forum for CVM, industry, and researchers to discuss regulatory science
- Completing one of the 10 required workshops under ADUFA II (Animal Drug User Fees Amendments II)

The program committee is currently in the process of evaluating feedback forms received at the meeting. The overall course grade was 8.3 (on scale from 1 to 10), indicating that it provided useful and fulfilling training for course participants. AAVPT is evaluating possible options for offering a similar course in the future. One option is to widen the scope of the workshop by including international regulatory requirements; another option is to have individual, more specialized course offerings, with an in-depth focus on only one aspect of drug development; a third option is to provide only a refresher course for the topics/areas that have changed since the first workshop.

Thank you to all the participants who made this inaugural event a well-attended and dynamic meeting. A big “Thank you” goes to all CVM speakers who were well prepared and eager to answer questions from the podium. The most heartfelt “Thanks” goes to Michele, Carol, Anthony and Ralph for all of their hard work, countless hours and many crisis-controls that we endured together in the last 10 months or so.

17th Biennial Symposium 2011

The 17th Biennial Symposium will be held May 22-25, 2011 at the Lowell Conference Center of the University of Wisconsin-Madison campus. Registration is now open. This is the second meeting for which we provide an option for on-line registration. Thanks to Anthony, it’s been a very seamless and useful transition for our organization!

For more information on the program and to register, please visit http://www.aavpt.org/17thBiennial.shtml, where you can register for the symposium and make a lodging reservation through the Lowell Conference Center. Full conference early-registration price is $450 if you register by May 6, 2011. After May 6, the registration cost will

CONTINUED ON PAGE 6
New Edition from Wiley-Blackwell!

Comparative Pharmacokinetics: Principles, Techniques and Applications
Second Edition
PROMOTION CODE: AAVPT

Now in a revised second edition, Comparative Pharmacokinetics: Principles, Techniques, and Applications presents the principles and techniques of comparative and veterinary pharmacokinetics in a detailed yet practical manner. Designed as a tool for ensuring that pharmacokinetics studies are properly designed and correctly interpreted, the book provides complete coverage of the conceptual basis of pharmacokinetics as used for quantifying biological processes from the perspectives of physiology and medicine. New chapters have been added on quantitative structure permeability relationships and bioequivalence, and a number of existing chapters have been significantly revised and expanded.

The second edition begins with the basic principles of physiology and then covers the primary approaches used in pharmacokinetic modeling. With broad human and animal species coverage, Comparative Pharmacokinetics is essential reading for those working in drug research and development, as well as those with advanced interest in pharmacology and toxicology in veterinary or comparative medicine.

Special Features
- Provides a detailed yet understandable reference
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- Includes new chapters on quantitative structure permeability relationships and bioequivalence, as well as fully revised and expanded chapters throughout
- Presents a fully rewritten chapter on simultaneous pharmacokinetic-pharmacodynamic modeling to reflect its newly widespread role in comparative medicine

Contents
Preface
Chapter 1: Introduction
Chapter 2: Principles of Drug Movement in the Body
Chapter 3: Quantitative Structure Permeability Relationships (QSPeR)
Chapter 4: Absorption
Chapter 5: Distribution
Chapter 6: Renal Elimination
Chapter 7: Hepatic Biotransformation and Biliary Excretion
Chapter 8: Compartmental Models
Chapter 9: Noncompartmental Models
Chapter 10: Nonlinear Models
Chapter 11: Physiological Models
Chapter 12: Dosage Regimens
Chapter 13: Simultaneous Pharmacokinetic-Pharmacodynamic Modeling
Chapter 14: Study Design and Data Analysis
Chapter 15: Design and Analysis of Bioequivalence Studies and FDA’s in vitro/in vivo (IVIV)
Chapter 16: Population Pharmacokinetic Models and the Bayesian Forecasting Applied to Clinical Pharmacokinetics
Chapter 17: Dosage Adjustments in Renal (and Hepatic) Disease
Chapter 18: Interspecies Extrapolations
Chapter 19: Tissue Residues and Withdrawal Times
Appendix

About the Editor
Jim Riviere, DVM, PhD, DSc (hon), ATS is the Burroughs Welcome Fund Distinguished Professor of Pharmacology, Alumni Distinguished Graduate Professor, and Director of the Center for Chemical Toxicology Research and Pharmacokinetics at North Carolina State University, and Editor of the Journal of Veterinary Pharmacology and Therapeutics.

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AAVPT Symposium 2011

2011 AAVPT 17th Biennial Symposium

May 22–25, 2011

University of Wisconsin-Madison

The Lowell Center Conference and Lodging Facility*

* Hotel reservations are not included with Symposium Registration and should be made by contacting the Lowell Center

610 Langdon Street, Madison WI 53703
Reservations: (866) 301-1753
Front Desk: (608) 256-2621
Fax: (608) 262-5445
Email: Lowell@ecc.uwex.edu

Program Highlights

Sunday, May 22
Aquaculture Session

Monday, May 23
Education Session
Large Molecule Session

Tuesday, May 24
Pharmacovigilance (PV) Session
Cytochrome P450 Session

Wednesday, May 25
Continuation of Cytochrome P450 Session

For more information visit http://aavpt.org/17thBiennial.shtml

Early-Bird Registration extended until May 6, 2011
increase to $550. Please note that the program committee specifically selected the Lowell Center in Madison for its central geographical location and a relatively low cost of lodging (all-inclusive with meals) and conference space. We hope to see many of you in Madison!

We have put together a very interesting scientific program, including sessions on aquaculture pharmacology, CYP-450 in veterinary medicine, pharmacovigilance, large molecule pharmacology, and veterinary pharmacology education. As this symposium marks the 33rd anniversary of the Academy, as well as, the 20th anniversary of our sister-organization, the American College of Veterinary Clinical Pharmacology, we are planning to make the symposium memorable by highlighting the history and activities of the founders and original members of both the Academy and the College during the meeting.

Many thanks to the program committee: John Burk, Dawn Boothe, Ralph Claxton, Cynthia Cole, Virginia Fajt, Anthony Lucas, Carol Davis, Katrina Mealey, Lesley Rausch-Derra and Michele Sharkey.

AAVPT MEMBERSHIP/BYLAWS COMMITTEE REPORT

Cynthia Cole

In the past year the Membership Committee completed a review of Regular members to determine who was eligible for Fellow member status. Invitations to become Fellow members were sent to eligible individuals, and the response was quite favorable. Spearheaded by Carol Davis, the Membership Committee put forward to the Executive Council (EC) a proposal to revise the by-laws regarding the composition of the EC. These changes were deemed necessary by the Membership Committee in order to address workload issues on the EC. For example, the position of Secretary-Treasurer has a particularly time-consuming workload, and, as such, it was recommended that the position be split into Secretary, Treasurer, and Treasurer-elect positions. The EC is still discussing the details, but the Membership Committee recommended that the EC would consist of a President, President-Elect, the immediate Past-President, Secretary, Treasurer, Treasurer-elect and four (4) Councillors. Other changes in the EC including the terms of each office were also discussed.

The desire to attract more members to the AAVPT, particularly those interested in actively participating on standing committees and the EC, continues to be the subject of much discussion. It is anticipated that the committee will address this issue in the coming year.

Please feel free to comment on any of these issues. Please send comments to ccole@piedmontpharma.com, and I will pass them along to the rest of the committee. If you are interested in joining the committee, please contact me as well. We would love to have you.

Committee Members: Cynthia Cole (chair), Carol Davis, Anthony Lucas, Virginia Fajt, Rainer Moser, Jane Owens, and Kirby Pasloske
The mission of the Veterinary Pharmacology Research Foundation (VPRF) is to provide grant funding to support research into new and currently approved medications for combating diseases of companion and food animals, projects that ensure the safety of food products from treated livestock, and training programs for veterinary pharmacologists.

Our first call for research grant proposals in 2010 yielded over 30 high quality applications. We are very pleased to report that in June of 2010, the first research grant was awarded to researchers from Cornell University for the development of a novel drug delivery method for treatment of Granulomatous Colitis of Boxer dogs.

In 2011, VPRF and the American College of Veterinary Internal Medicine (ACVIM) Foundation partnered once again to grant up to $18,000 for veterinary pharmacology research projects. Any clinician or scientist with an interest in veterinary pharmacology was eligible to serve as Principal Investigator on the proposal. As this grant was a partnership between veterinary internists and VPRF, collaborations between pharmacologists and Diplomates of ACVIM were strongly encouraged. The deadline for submission was March 15, 2011, and the review process is currently underway.

These grants are made possible by the generous donations from AAVPT, Pfizer Animal Health, Torpac Inc. and members of AAVPT. The VPRF board would like to thank all of you who helped make this possible through your generous contributions. We also hope that AAVPT members will continue to support this foundation in our efforts to fund additional veterinary pharmacology research grants in the future. The Foundation accepts donations of cash and securities at any time. You can also support the foundation by leaving a charitable bequest in your will. Please visit our section of the AAVPT website for more information or feel free to contact Jane Owens (owens_jane_g@lilly.com) or Dan Gingerich (dgingerich@imulan.com) for more information on VPRF.

President
Jane G. Owens
Elanco Animal Health
2001 W. Main St
Greenfield, IN 46140
owens_jane_g@lilly.com

Secretary-Treasurer
Dan Gingerich
2219 Wilmington Road
Lebanon OH 45036
dgingerich@imulan.com

Board Members
Joe Gloyd
Anthony Lucas
Mark Papich
USP DELEGATE REPORT

Carol Davis

This report summarizes what I received from Drs. Mark Papich and Marilyn Martinez on activities at USP. According to Mark, there is not much to report at this time. As everyone knows, the former standards committee was eliminated, and all the veterinary drugs were moved into the Small Molecules 3 committee (SM3). Mark is the token veterinary member of SM3, and veterinary drugs are just one small component of this much larger committee. He was unable to attend the first face-to-face meeting, and there were no veterinary issues discussed at that time. The second face-to-face meeting is scheduled for May 3-4, and Mark says he will have about an hour on the agenda to bring up veterinary concerns and to discuss unfinished business from the last cycle. He says he will propose a separate veterinary expert panel, which will be a cross-cutting panel to tackle the veterinary issues that arise from the other committees (nomenclature, formulations, general chapters, compounding, etc). This will hopefully provide us with a little better visibility as we go forward. There has already been a separate veterinary drug expert panel formed as well, specifically to address the Biopharmaceutics Classification System (BCS) issue. Because it was concluded that BCS will not work for animals (Mark reported this at the Chemical Reference Standards (CRS) meeting and is preparing a written report on this study), this panel has evolved into a “Veterinary Drug Solubility” panel to just look at solubility issues. The panel met on February 10, 2011 in Rockville. Marilyn reported that concurrence was achieved during the February 2011 face-to-face meeting of the Veterinary Drug Solubility Expert Panel. Permeability criteria will not be considered due to the lack of information and the lack of validated in vitro systems to support such assessments in veterinary species. The conditions for testing solubility criteria are currently under discussion. Because of uncertainties associated with gastric volume (particularly in the dog), the drug substance will either be classified as soluble or not soluble. The expression “highly soluble” will not be used. The Expert Panel agreed that the stimuli article would first target dogs and cattle because the approved drug products for these species would be most impacted by the availability of solubility criteria. Once there is an agreement on the proposals put forth in the stimuli article, a general chapter will be developed. As additional animal species are added to these deliberations, the general chapter will be amended.

NEWS

Peter Eyre awarded honorary degree

Dr. Peter Eyre, professor and dean emeritus of the Virginia-Maryland Regional College of Veterinary Medicine received a doctorate degree—honoris causa, from the University of Edinburgh for contributions to pharmacology and the profession in Britain, Canada, and the United States. The degree was conferred during a graduation ceremony held in Edinburgh where he presented the graduation address to the medical, health sciences and veterinary graduates. The conferral coincided with the 50th anniversary of Dr. Eyre's original veterinary degree.

Marion Ehrich receives Pfizer Award

Dr. Marion Ehrich, co-director of the Laboratory for Neurotoxicity Studies and professor of pharmacology and toxicology at the Virginia-Maryland Regional College of Veterinary Medicine, received the Pfizer Animal Health Award for Research Excellence during ceremonies associated with the college’s 2010 Research Symposium. The purpose of this award is to “foster innovative research, on which the scientific advancement of the profession depends, by recognizing outstanding research effort and productivity.”

VPRF Fund-raising Silent Auction

May 24, 2011

The Veterinary Pharmacology Research Foundation will host the Second Annual Fund-raising Event at the AAVPT 17th Biennial Symposium during the Annual Banquet on the evening of Tuesday, May 24, 2011 in Madison, WI. There will be a silent auction during this event to raise money to support research into new and currently approved medications for combating diseases of companion and food animals, projects that ensure the safety of food products from treated livestock, and training programs for veterinary pharmacologists.
OBITUARY

Waldir Pedersoli

We are sad to report that one of our long-standing Emeritus Fellows, Dr. Waldir Pedersoli, passed away in 2009. He received his DVM from the University Federal of Minas Gerais, Brazil, and he received his MS and PhD degrees from the University of Illinois. Dr. Pedersoli was a professor of pharmacology at Auburn University, College of Veterinary Medicine, from 1967 to 1987. He moved to the Washington, DC area in 1988 to work as a researcher for the Food and Drug Administration, Center for Veterinary Medicine in Beltsville, MD. He retired in the late 1990s. He had been diagnosed with Alzheimer's disease in 2004. We had not heard of his passing until very recently. We offer our sympathy to his wife and family.

FROM THE EDITOR

Maya M. Scott

The newsletter is provided twice a year for the members of AAVPT. Please let me know if you have any news or information to share with the organization.

Fall Newsletter correction:
Regarding the Fall USP delegate report, Dr. Marion Ehrich has been selected to serve on the USP Counsel of Experts Toxicology committee. We apologize for the omission.
The objectives of the Academy are:

To support and promote the education and research in comparative pharmacology, clinical veterinary pharmacology and other aspects of pharmacology of interest to the veterinary profession.

To sponsor a periodical Journal of the Academy which will publish reviews, summaries and original treatises on all aspects of veterinary pharmacology and therapeutics. The Journal of Veterinary Pharmacology and Therapeutics shall be an official instrument of the Academy.

To sponsor and conduct workshops, symposia or other scientific and educational meetings in veterinary pharmacology and therapeutics.

To enhance the exchange of educational materials and ideas among veterinary pharmacologists.

To organize committees of experts to research and make recommendations to the profession on current problems in veterinary therapeutics.