THE SCOPE

Vol. 19, No. 3, Summer 2003

Highlights of the STP 22nd Annual Symposium

Savannah

The Society of Toxicologic Pathology held its 22nd Annual Symposium in Savannah, Georgia in mid-June 2003. Of the 503+ attendees, 127 were from outside of the U.S.

NTP Satellite Symposium

An NTP Satellite Symposium was held on Saturday, June 14, 2003. The unique exercise involved presentation of 13 Web cases followed by 24 unknown cases. Voting participants were provided with audience response units to register their votes on each case. The results of the initial votes for each case were immediately projected. The participants revoted on each case following a brief presentation of the spectrum of related lesions. The exercise was very popular with 98% of the voting participants indicating that they would like to have similar presentations at a future STP Annual Meeting. The demographic and voting results can be found at the following URL: **http://dir.niehs.nih.gov/dirlep/**.

Continuing Education Courses

"Digital Microscopy and Analysis," and "Toxicologic Pathology and the Development and Validation of Biomarkers of Risk of Effect" were the topics of continuing education courses presented on Sunday prior to the beginning of the main symposium.

Dr. Andres Kriete addressed the basics of digital microscopy followed by **Dr. Badri Roysam**, who gave a presentation of automated image analysis. **Dr. Mark Tengowski** provided information on advanced optical techniques and considerations and **Dr. P.C. Cheng** gave the last presentation on advanced fluorescence microscopy.

Dr. Susan G. Emeigh Hart chaired the afternoon session in which **Dr. Graham Betton** provided an overview of biomarker development. **Ms. Annie M. Jarabek** discussed the application of biomarkers to environmental risk assessment as they extend the range of observation. The selection and validation of troponins as biomarkers of cardiac injury was presented by **Dr. Eugene Herman**. **Dr. Lester Schwartz** gave the final presentation, "Selection and Validation of Biomarkers of Vascular Injury."

continued on page 2

INSIDE

FROM THE PRESIDENT

Nancy Gillett

Shortages

When I think about toxicologic pathology today, the term "shortage" applies to many different areas. We have all noticed the shortage of younger qualified pathologists as we seek to fill job openings. Fewer individuals are entering pathology at a time when the opportunities seem greater than ever before. Companies are recognizing the value of well-trained pathologists in wider roles than previously, from discovery research through the late stages of drug development, for all areas of chemical research, and finally in many senior strategic decision making positions. Yet the number of people available to get the work done is steadily shrinking. The number of faculty available to train the next generation of toxicologic pathologists is also rapidly declining, as individuals retire, or seek more profitable positions in industry. The shortage of pathologists has been an area of concern to both STP and several sister societies, and is well quantified in the recent survey done jointly by the ACVP and STP.

The second shortage that comes to mind is funding. A partial solution to the shortage of toxicologic pathologists is funding: funding for education of veterinary students and residents; funding for training programs; funding for summer internships; and funding

continued on page 4

Symposium Highlights

continued from page 1

Symposium Overview—The Human Genome: Implications for Toxicologic Pathology and Carcinogensis

The main symposium began on Monday with **Dr. John Robertson** addressing the Annual Meeting attendees.

The focus of this year's symposium was the human genome and its relative implications for toxicologic pathology and carcinogensis. The sessions and issues discussed were highlighted in the Winter 2003 *Scope* and detailed in the program book for the meeting. The scientific session speakers' presentations will be published in the 2003 *Toxicologic Pathology* supplement. There were six symposiums presented in a four-day period. The session summaries are as follows:

The Monday morning session focused on the role of completion of the human genome in defining new directions in cancer research. The afternoon discussion focused on SNP mapping of human disease alleles and the utility of SNP maps and integrated transcript data in the prediction of efficacy/safety responses and in the development of treatment strategies.

The role of animal models of human cancer in the investigation of disease pathogenesis, testing therapies, prevention strategies, and assessing cancer composed the third session.

The fourth and fifth sessions reviewed methods, applications, and research findings in the field of molecular pathology of cancer in humans and rodents. It also covered conceptual overviews of the uses of molecular profiling and biomarker profiles in cancer screening, treatment population segregation, and the approaches and limitations of biomarker development during drug discovery and development.

The concluding session "Future Directions in Toxicologic Pathology" looked at new ways to address old problems such as the examination of protein and DNA adduct profiles and the importance of a threshold to discussion on cell signaling in lesions of interest in toxicologic pathology analyses.

Town Hall Meeting—Establishing NOELs and NOAELs

June 16, 2003

Panel Participants:
Dr. David Jacobson-Kram (FDA-CDER),
Dr. Robert Maronpot (NIEHS),
Dr. Laura Dill Morton (Pfizer),
Dr. Terry Peters (FDA-CDER),
Dr. Darrell Tuomari (Schering-Plough),

Moderator: **Dr. Ricardo Ochoa** (Pfizer)

Dr. Jacobson-Kram discussed the use of No Observed Adverse Effect Levels (NOAELs) by the FDA when setting the First Dose in Humans. The NOAEL is first determined for the most sensitive animal species. The maximum dose for early clinical trials is then determined on a case-by-case

continued on page 3

STP Newsletter
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The 22nd Annual Symposium of the Society of Toxicologic Pathology

Symposium Committee

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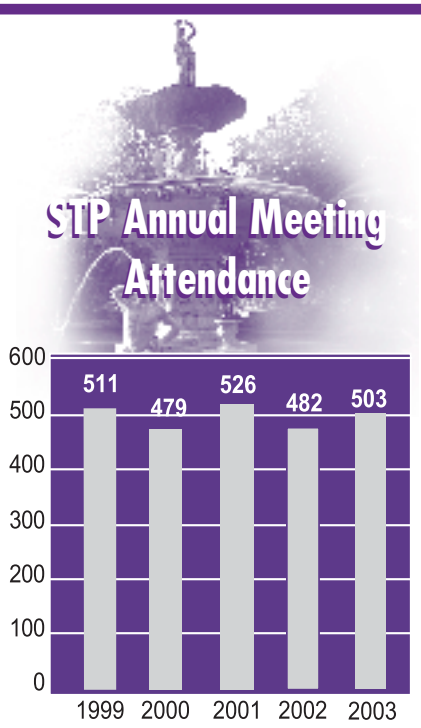


IATP ACTIVITIES

The Board and Fellows of the International Academy of Toxicologic Pathology (IATP) met during the STP 2003 Annual Symposium in Savannah, Georgia and established a short list of planned activities. For more details regarding the IATP activities, please visit the STP Web site posting of *The Scope*.

HEPATOTOXICITY TO BE FOCUS OF STP 23RD ANNUAL SYMPOSIUM

June 13–17, 2004 Grand America Hotel, Salt Lake City, Utah

The liver has been studied extensively because it is a common target organ in animals administered compounds being developed by the pharmaceutical or chemical industries. However, our understanding of *toxicity* in regard to the potential for human or animal (where relevant) risk is still limited. Due to this lack of clarity, regulators are often constrained to view any liver toxicity in preclinical studies as a significant hazard. Effects of Xenobiotics on the liver need to be identified and classified as either a consequence of exaggerated pharmacology, or chemical structure toxicity. We are then obligated to determine, as best we can, whether the toxicity is only relevant to our test species and what, if any, is the likely effect in humans.

The recent development of new technologies for assessing hepatotoxicity (including the "omics" revolution) and their potential application to risk assessment calls for the STP to dedicate a symposium to this important issue. This requires addressing both older and newer perspectives on the nature and management of hepatotoxic risk, including an understanding of the point of view of the different regulatory bodies, and a look to the near and distant future. Consideration of cutting-edge technologies, as well as revisiting older technologies from a new perspective will make this symposium a can't miss event!

The Continuing Education Courses also promise to add variety to this exciting program in 2004. They will focus on two important areas, the often neglected special senses (including eye, ear, and nasal tissues), and the emerging interest in immunotoxicity (in regard to both the science and regulatory guidelines).

The focus of the 2004 symposium on the liver, one of the principal organs of interest to toxicologic pathologists, is overdue. Holding the symposium in Salt Lake City, one of the most beautiful locations in the country, will only add impetus to the many reasons to attend this event. The symposium committee is committed to putting together a world-class curriculum and looks forward to seeing you in Utah in 2004.

Attendees are eligible for continuing education credits for both CE Courses and the entire Scientific Session Program. Please visit the STP Web site to register for the meeting.

NTP Satellite Meeting

June 12, 2004

"Comparative Pathology of the Liver"

NOELs and NOAELs

continued from page 2

basis considering NOAELs from preclinical studies, the availability of biomarkers to monitor subjects for toxicity, and other available information. This maximum dose is anticipated to be the highest dose that would not cause unacceptable effects in human subjects. CDER does not believe that further discussion by the STP of how to determine NOAELs or the maximum dose for early clinical trials would be useful at this time.

Dr. Jacobson-Kram defined the NOAEL as a dose at which there are no detectable adverse effects.
Dr. Morton reviewed the World Health Definition of adverse effect. The World Health Organization defines an adverse effect as one that impairs functional capacity, impairs capacity to adapt to stress, or increases susceptibility to harmful effects of other environmental influences.
Dr. Morton pointed out that different definitions of "adverse" contribute to confusion about the identification of NOAELs in preclinical studies.

continued on page 5

2003 Annual Meeting Contest Winners

Winner of the Annual Meeting Survey Raffle:
Dr. Rodney Frank

Winner of the Get-A-Member Contest:
Dr. Wanda Hascheck-Hock

Winner of the Update Your Membership Profile Raffle:
Dr. Eric DeBruyne

For more information regarding the contests and prizes, please see the on-line version of *The Scope*.

22ND ANNUAL BUSINESS MEETING

Dr. Wanda Haschek-Hock, STP Secretary/Treasurer, reported during the Annual Business Meeting that STP had a $16,349 net gain in 2002 despite the downturn in the Society's financial investments and the decline in revenues. The gain was achieved by reducing overall expenses. Ending 2002 total current assets (cash, etc.) were $271,601 and investments were $305,379 resulting in total assets of $576,980 with total current liabilities of $114,113 and total net assets of $463,867. The total assets represent approximately 75% of the Society's operating budget, which is standard for a non-profit society such as STP.

Dr. Hascheck-Hock reminded the attendees that the Society has financial obligations to the facilities that the Society utilizes during the Annual Meeting; thus, it's important that Annual Meeting attendees stay at the headquarters hotel and utilize the reserved room block so the Society can meet its financial commitments.

Dr. John Robertson, STP President, informed the attendees at the Annual Business Meeting that though the Society is financially stable, the Fundraising Committee was initiating a "Capital Campaign" to raise the funds necessary for the educational activities set forth by the Education Task Force and approved by the Executive Committee.

Congratulations to the 2003 Student Award Winners

Young Investigator Winners (from left) Michael Thibodeau, Elmarie Bodes, John Robertson (President), Susan Hester.

Young Investigator Award Winners

First Place:
Michael Thibodeau
Second Place:
Susan Hester
Third Place:
Elmarie Bodes

2003 Student Travel Award Winners

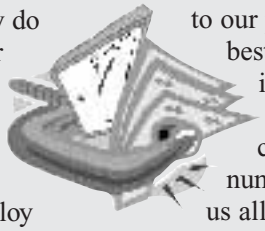
(Pictured on next page)

Elmarie Bodes
Susan Elmore
Martin Fridmann
Rajesh Kumar
Maozzam Kahn
Tanasa Osborne
J. Todd Painter
Banalata Sen
Michael Thibodeau
Gaurav Tyagi
Charles Wood
Charles Randal Partridge
Amy Wang

From the President

continued from page 1

for continuing education. The Educational Task Force under the direction of **Susan Hart** has recently completed a comprehensive list of objectives to enhance the impact on education by the STP. Several of the action items require more focused funding for many different venues of education. Our past president, **Dr. John Robertson**, has committed to an extraordinary level of fund-raising during his tenure as Past-President. The ACVP has committed to a capital fund-raising effort that is also greater in magnitude than previous years; a small joint task group is examining the goals of each organization to be sure that they do not compete with each other for funding. However this need for increased funding comes at a time of economic downturn for the country and many of the industries that employ toxicologic pathologists. In addition, the many mergers and acquisitions in the pharmaceutical and biotech industries have resulted in a decrease in the number of large companies available as a source for significant funding. Therefore the prospect of an actual decrease rather than increase in charitable donations by companies appears possible.



Finally there is a shortage of time. Those of us in the field of toxicologic pathology, regardless of the job type, are stretched very thin and being impacted by the shortage of pathologists and the shortage of funding to hire additional people. In an era of downsizing and mergers most individuals have to do the same job with less people, and yet often have higher productivity goals. We all have more than enough to do, and the demands of the job often make it difficult to consider volunteering for additional activities and responsibilities.

So in this era of "shortages," what is the solution? The solution that I see is for all of us to become involved at whatever level we can to give back to our profession. One of the best ways is through involvement in STP. Now this solution may seem counterintuitive as the number of shortages make us all feel that we have no more to give. But if we all give a little, we can have a tremendous impact. If you are in a senior position and able to influence funding decisions for your company, please consider substantial contributions to the STP to fund some of these initiatives to increase the number of toxicologic pathologists.

If you are able to speak at a local college or veterinary school, please accept the opportunity to expose a number of young people to the exciting career opportunities available in toxicologic pathology; a PowerPoint presentation is available through STP. If you have an interest in an STP committee or activity, please make that interest known to the staff at AIM or your colleagues on the committee; we welcome fresh ideas and new faces. If you are able to mentor a young summer intern at your facility, please be sure that your externship is known and advertised through the STP Web site in order to help find the best possible candidate. If we are all able to mentor and influence one bright young person to consider and ultimately pursue an exciting career in toxicologic pathology, many of these shortages will disappear. The profession will be stronger, STP will be stronger, and some of us may ultimately be able to work only five days per week instead of seven!

Nancy Gillett

STP Annual Meeting June 15–19, 2003
Savannah, Georgia

Student Travel Award Winners (left to right) Charles Partridge, Susan Elmore, Martin Fridmann, John Robertson (President), Banalata Sen, Elmarie Bodes, Amy (Hui-Shan) Wang, Moazzam Khan, Gaurav Tyago, receive recognition.

Visit www.toxpath.org to learn more about 2004 award opportunities

Incoming President Nancy Gillett receives gavel from outgoing John Robertson (President).

Abbot Grant Winner, Elmarie Bodes, receives certificate from John Robertson (President).

NOELs and NOAELs

continued from page 3

Drs. Peters and Ochoa responded that identification of NOAELs in animals must be made in context using the entire weight of evidence, the proposed indication, and the target patient population. Dr. Peters added that statistical significance by itself is not sufficient to label a finding adverse. The severity of an effect is critical in determining if an effect is adverse. She stated that the FDA is interested in the sponsor's views of NOAELs, but that the Agency will make its own assessment.

Dr. Jacobson-Kram reiterated that the FDA is looking for the highest dose that will not produce unacceptable adverse effects in humans, not tolerable side effects (e.g. salivation). Side effects that may be tolerable in severely ill patients with life-threatening disease may not be tolerable in normal volunteers.

After considerable audience discussion, most participants believed that it was difficult or impossible to produce generic guidelines for determining NOAELs. Reason must be applied to each case using all available information. **Dr. Harold Davis** summed up the majority opinion by stating that he would be worried if we could classify findings as adverse or not in the absence of information about other findings, expected pharmacology, proposed indication, intended patient population, etc.

Dr. Ochoa told the audience that the STP had been requested to address the determination of NOAELs in a position paper, and asked for the audience's thoughts about this proposal. The general feeling of the audience was that the STP should not attempt to clarify the meaning of NOAELs, but that better methods were needed to predict human toxicity using preclinical models.

New Members

Welcome!

Barlow, Keith	*Georgetown University*
Castleman, William	*University of Florida*
Dambach, Donna	*Bristol-Myers Squibb*
de Vera, Maria Cristina	*Hoffmann-La Roche Ltd.*
Diaz-Bayon, Aida	*Sanofi-Synthelabo*
Frazier, Kendall	*GlaxoSmithKline*
Fridmann, D. Martin	*U.S. Environmental Protection Agency*
Giddens, W. Ellis	*Pathology Consulting*
Halm, Sabine	*Abbott GmbH & Co. KG*
Hill, Georgette	*National Institute of Environmental Health Health Sciences*
Khan, Moazzam	*U.S. Environmental Protection Agency*
Malarkey, David	*National Institute of Environmental Health Sciences*
Merrill, Christine	*GlaxoSmithKline*
Osborne, Tanasa	*University of Illinois*
Pilling, Andrew	*Huntingdon Life Sciences*
Pyrah, Ian	*AstraZeneca*
Rodriguez, Juan	*Pharmakine, Ltd.*
Schorsch, Frédéric	*Bayer CropScience*
Stanley, James R.L.	*PAI/Charles River Laboratories*
Trueblood, Esther	*ICOS Corporation*
Tyagi, Gaurav	*College of Veterinary Medicine*
Van Tongeren, Susan	*Boehringer Ingelheim*
Wako, Yumi	*Mitsubishi Chemical Safety Institute Ltd.*
Weiler, Horst	*Philip Morris Research Laboratories GmbH*
White, M. Randy	*Bristol-Myers Squibb*
Wood, Charles	*Wake Forest University School of Medicine*

EXTERNAL AFFAIRS COMMITTEE SUMMARY OF STP LIAISON REPORTS MAY 2003

George l. Foley, Chair

The External Affairs Committee has completed the second year of the re-organized STP liaisons with the reappointment of **Drs. Keith Harris** (ACVP liaison) and **David Eisenbrandt** (CLA liaison). In the upcoming year, the liaison group will work to become better integrated with the Regulatory Affairs Committee, continue to submit liaison reports to the newsletter and the STP Web site, and to provide updates to the Council from allied societies. Attached are seven summaries from the nine liaisons. Full texts of the External Affairs Committee and the liaison reports are posted on the STP Web site.

American College of Toxicology (ACT), *Laura Dill Morton*: The 24th Annual Meeting of the ACT will be held in Washington D.C. from **November 2–5, 2003**. **Drs. Bill Hall and Donald Dungworth** will chair the STP symposium which will cover various topics related to inhalation toxicology, respiratory pathology, and imaging techniques. The ACT council designated an *ad hoc* committee chaired by **Leigh Ann Burns Naas** to discuss the possibility of sponsoring a course on pathology for non-pathologists that would include participation with the STP. Suggested framework and the times of the course are presented on the STP Web site.

American College of Veterinary Pathologists (ACVP), *Keith Harris*: The Council continues to devote much of its time to implementation of the College's strategic plan. Major components of the plan are recruitment, increasing visibility of veterinary pathology, and increasing the Endowment Fund. Other activities include plans to initiate an on-line compensation/employment survey this summer, and conversion of *Veterinary Pathology* to electronic manuscript submissions. Electronic publication of the Journal commenced March 1, 2003. **Dr. Reid Patterson** is working with the ACVP Council and the ACVP representative to the American Board of Veterinary Specialties to obtain approval of the Toxicologic Pathology subspecialty.

CropLife America (CLA), *David Eisenbrandt*: Key issues for CLA Human Health and Risk Assessment Round Table (HART) scientists are the EPA's Draft Final Guidelines for Carcinogen Risk Assessment as well as the Supplemental Guidance for Assessing Cancer Susceptibility for Early-Life Exposure to Carcinogens. Other ongoing issues for CLA HART scientists are related to existing and planned regulatory guidelines for testing of chemicals for potential health effects. Opportunities for STP actions of support of CLA are to publish the STP commentary on neurotoxicity and to be instrumental in influencing regulatory agencies in the development of a more rational approach to product safety testing.

International Life Sciences Institute (ILSI), *Charlotte Keenan*: HESI sponsored two scientific sessions at the 2003 ILSI Annual Meeting; "Toxicokinetics of Drugs and Chemicals in Children" and "Emerging Computational Tools for Toxicology." Additional HESI and RSI highlights are included in its entirety in the liaison report on the STP Web site. The North American Control Animal Database (NACAD) conducted a survey on trends in rat strain selection for toxicity and carcinogenicity studies. The results were presented at the annual STP meeting. ILSI Seminars on Advanced Pathologic Techniques will

continued on page 7

Employment Opportunities

- **Assistant Professor of Anatomic Pathology (tenure track)**
  School of Veterinary Medicine, University of California, Davis
  Contact: N. James MacLachlan, Chairman, Department of Pathology, Microbiology, and Immunology, School of Veterinary Medicine, University of California, Davis, Davis, CA 95616, Attn: Donna Roggenkamp. AA/EOE

- **Veterinary Pathologist, CTBR, Montreal, Canada**
  Contact: Nichola Harding
  Talentmark Executive Resourcing, King House,
  5-11 Westbourne Grove, London W2 4UA.
  Phone: +44 (0)20-7229 2266 Fax: +44 (0)20-7229

For details and deadlines on the above opportunities, visit www.toxpath.org

Liaison Reports

continued from page 6

be presented on **November 15, 2003** at the ACVP meeting.

National Toxicology Program (NTP), *Ron Herbert*: The NTP Board of Scientific Counselors Technical Reports Review Subcommittee peer reviewed six NTP Technical Reports of NTP rodent toxicity and carcinogenicity studies. NTP's Genetically Modified Model (GMM) series was unveiled at the spring meeting. The studies of aspartame and acesulfame potassium will be the first studies reported in the new series. In February 2003 NTP hosted a workshop, "Genetically Modified Rodent Models for Cancer Hazard Identification: Selecting Substances for Study and Interpreting and Communicating Results." The goals of the workshop and upcoming events are posted on the STP Web site. NTP is creating a new database to allow searches of its study data using the Web. The database can be accessed from the NTP homepage (http://ntp-server.niehs.nih.gov) by selecting "NTP Study Information." Available data on individual studies and pathology with links to incidence rates and individual animal pathology data can be searched in this database.

Pharmaceutical RMA (PhRMA), *Darrell Tuomari*: **Lisa (Alisia) Miles** has been appointed Director of Emergency Preparedness. This is a new position that has been created at PhRMA. Her role will be to help counter terrorism due to the use of biological or chemical agents. A Joint DruSafe and Drug Metabolism-PhRMA Fall Workshop entitled "Covalent Drug-Protein Interactions: Implications in Drug Discovery and Development," was held **September 7–9, 2003**. Ongoing DruSafe Technical Working Groups include: Emerging technologies, immunotoxicity, safety pharmacology, carcinogenicity, and genotoxicity.

Society of Quality Assurance (SQA), *Lynda Lanning***:** The 19th Annual Meeting of the Society of Quality Assurance will be held on **October 12–16, 2003** in Arlington, VA. The STP will sponsor a session entitled "Toxicologic Pathology: Current Compliance Considerations." A working party of the Clinical Committee of the British Association of Research Quality Assurance has prepared a document, which identifies the systems and procedures it would expect to be in place within an organization that conducts analysis of samples from clinical trails in compliance with the requirements of GCP. The E.U. has signed up 10 new members to make 25-nation market in 2004. For STP members unfamiliar with the SQA and for those seeking additional information of interest, log on to the STP Web site for the complete report.

FROM THE EDITOR

This issue of *The Scope* marks the departure of **Lynda Lanning** as Senior Editor. Lynda has been an editor of the newsletter for four years, the last two as Senior Editor. Under her direction and with the addition of the Association Innovation and Management (AIM) group, *The Scope* has taken on a "leaner, more jazzier" appearance. Articles are highlighted in the newsletter and detailed on the Web. The numbers and quality of graphic designs have much improved. But most importantly, Lynda has maintained and improved the quality of the *The Scope*, standing by her pledge to bring the membership the type of newsletter we have come to expect.

Lynda Lanning

As I begin my tenure as Senior Editor, it is my intention to maintain the quality and traditions of the newsletter. I encourage the membership to use their newsletter as an instrument for the dissemination of their ideas, opinion, and items of interest. With active participation of the membership, our newsletter can only get better. I look forward to hearing from you in the upcoming year.

Carol Thompson
Senior Editor, *The Scope*

2003 2004

For a listing of upcoming events visit www.toxpath.org

The Society of Toxicologic Pathology would like to thank the following Society Sponsors for their contributions.

(as of July 1, 2003)

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